

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----x
ABBOTT LABORATORIES, ABBOTT :
DIABETES CARE INC., and ABBOTT :
DIABETES CARE SALES CORPORATION, :
Plaintiffs, :
: 15 Civ. _____
: **COMPLAINT AND JURY DEMAND**
: **-against-**
: **ADELPHIA SUPPLY USA; YUDAH NEUMAN** :
A/K/A LENNY NEUMAN; REUVEN SOBEL :
A/K/A CHAIM SOBEL; MOSES NEUMAN; :
SHMUEL LEZELL; SAVE RITE MEDICAL.COM: :
LLC; MARC KAPLAN; MATRIX :
DISTRIBUTORS, INC.; CHRISTOPHER :
BENEVENT; SETH GRUMET; H&H :
WHOLESALE SERVICES, INC.; HOWARD :
GOLDMAN; LORI GOLDMAN; PAPOUTSANIS :
USA, LLC D/B/A VIP INTERNATIONAL – :
DROGARIS; GEORGE DROGARIS; OSD :
CAPITAL, INC. F/K/A FARNE'S ENTERPRISES :
CORPORATION; :
OVERSTOCKDRUGSTORE.COM LLC D/B/A/ :
SIMPLEMED SUPPLY; RICK EVENSON; :
KEVIN PLUMB; BUDGET HEALTH :
CORPORATION D/B/A BUDGET DRUGS :
PHARMACY; JOHN FANDETTI; ROBERT :
NEWMYER; MARIA FANDETTI; LORI BLUE; :
ANTHONY MEOLA; MARK D. HENKIN; :
DREAM CEREAL INC. D/B/A :
DIABETESSUPPLIES4LESS.COM; DOUGLAS :
HAUCK; BERKELEY DRUGS INC.; MAJID :
HAMEED; EUGENE HA; CAREWAY :
PHARMACY INC.; ANATOLIY FAIN; :
HARRICO-GALLER DRUG CORPORATION; :
JOHN GALLAGHER; HABER J&N INC. D/B/A :
THE MODERN CHEMIST; NAOMI HABER; :
JERRY HABER; NORSTRAND PHARMACY, :
LLC D/B/A VANDERVEER PHARMACY; :
SARATHCHANDRA ADUSUMALLI; :
HEMAGIRI GAYAM; LEV RX CORP. D/B/A :
KIRA'S PHARMACY; KIRA LEVKOUSKAYA; :
ELIYAHUS PHARMACY, INC.; ILIAS :
-----x

MLABASATI; GLOBAL CARE PHARMACY, :
INC.; D.K.Y. ENTERPRISES, INC. D/B/A 8TH :
AVENUE PHARMACY; KIM PING JIM; TGIS :
PHARMACY, INC. D/B/A SUNRISE FAMILY :
PHARMACY; SAJID JAVED; BAY PHARMACY: :
INC.; IRENE PIKER; B & T MARLBORO :
PHARMACY, INC.; ANATOLY :
GOROKHOVSKY; LARKE DRUGS, INC. D/B/A :
110 PHARMACY & SURGICAL; PRASAD :
VENIGALLA; LA RUCHE PHARMACY, INC.; :
SUNIL B. PATEL; ESTATES PHARMACY, INC.;:
MOHAMMED NURUDDIN; and JOHN DOES 1- :
10, :
: Defendants. :
-----x

Plaintiffs Abbott Laboratories, Abbott Diabetes Care Inc., and Abbott Diabetes Care Sales Corporation (collectively, “Abbott”), by and through their attorneys, Patterson Belknap Webb & Tyler LLP, for their Complaint against Defendants Adelphia Supply USA; Yudah Neuman a/k/a Lenny Neuman; Reuven Sobel a/k/a Chaim Sobel; Moses Neuman; Shmuel Lezell; Save Rite Medical.com LLC; Marc Kaplan; Matrix Distributors, Inc.; Christopher Benevent; Seth Grumet; H&H Wholesale Services, Inc.; Howard Goldman; Lori Goldman; Papoutsanis USA, LLC d/b/a VIP International – Drogaris; George Drogaris; OSD Capital, Inc. f/k/a Farnes Enterprises Corporation; Overstockdrugstore.com LLC d/b/a/ SimpleMed Supply; Rick Evenson; Kevin Plumb; Budget Health Corporation d/b/a Budget Drugs Pharmacy; John Fandetti; Robert Newmyer; Maria Fandetti; Lori Blue; Anthony Meola; Mark D. Henkin; Dream Cereal Inc. d/b/a Diabetessupplies4less.com; Douglas Hauck; Berkeley Drugs Inc.; Majid Hameed; Eugene Ha; Careway Pharmacy Inc.; Anatoliy Fain; Harrico-Galler Drug Corporation; John Gallagher; Haber J&N Inc. d/b/a The Modern Chemist; Naomi Haber; Jerry Haber; Norstrand Pharmacy, LLC d/b/a Vanderveer Pharmacy; Sarathchandra Adusumalli; Hemagiri Gayam; Lev RX Corp. d/b/a Kira’s Pharmacy; Kira Levkouskaya; Eliyahus Pharmacy,

Inc.; Ilias Mlabasati; Global Care Pharmacy, Inc.; D.K.Y. Enterprises, Inc. d/b/a 8th Avenue Pharmacy; Kim Ping Jim; TGIS Pharmacy, Inc. d/b/a Sunrise Family Pharmacy; Sajid Javed; Bay Pharmacy Inc.; Irene Piker; B & T Marlboro Pharmacy, Inc.; Anatoly Gorokhovsky; Larke Drugs, Inc. d/b/a 110 Pharmacy & Surgical; Prasad Venigalla; La Ruche Pharmacy, Inc.; Sunil B. Patel; Estates Pharmacy, Inc.; Mohammed Nuruddin; and John Does 1-10, allege as follows:

NATURE OF THE ACTION

1. This is an action for trademark infringement, fraud, racketeering, unfair competition, and other illegal and wrongful acts brought against Defendants who have distributed and sold in the United States diverted international blood glucose test strips that are illegal to sell in the United States.

2. Abbott sells medical equipment for diabetic patients, including the well-known FreeStyle® and FreeStyle Lite® blood glucose test strips (collectively, “FreeStyle test strips”), which are used by diabetics to monitor their blood glucose levels. Millions of individuals with diabetes use FreeStyle test strips on a daily basis to monitor their blood sugar and help them control their disease.

3. In disregard of the law, Defendants are conspiring to import diverted international FreeStyle test strips whose labeling has not been cleared by regulators for sale in the United States and is likely to confuse U.S. consumers.

4. The Defendants are passing these unapproved test strips off to unsuspecting U.S. consumers to receive insurance reimbursements that they are not entitled to. In doing so, Defendants have defrauded and continue to defraud Abbott, other manufacturers of test strips, and insurance companies, third-party payors, and Medicaid and Medicare.

5. At the center of this conspiracy are several wholesalers (the “Distributor Defendants”) who import large volumes of diverted international FreeStyle test strips for

distribution to pharmacies (including the “Pharmacy Defendants” named below) throughout the United States. The Pharmacy Defendants are selling the diverted FreeStyle test strips to U.S. consumers and submitting fraudulent reimbursement claims to insurance companies, Medicare, Medicaid, and other third-party payors, claiming to have sold domestic FreeStyle test strips, which, unlike diverted international test strips, are eligible for reimbursement.

6. These false submissions caused—and continue to cause—Abbott to pay out, wrongfully, millions of dollars in rebates.

7. Due to the differences between U.S. and international insurance, reimbursement, and rebate practices, Abbott sells FreeStyle test strips outside the United States at markedly lower list prices. Defendants capitalize on these pricing differences to receive undeserved reimbursement payments from insurers. Defendants further know that Abbott pays rebates to insurers for those undeserved reimbursement payments. The Distributor Defendants and Pharmacy Defendants have a long-standing relationship, through which they agreed to purchase diverted FreeStyle test strips from foreign countries at these lower prices and then dispense them to consumers at higher U.S. retail prices for the purpose of receiving fraudulent reimbursement payments from the consumers’ insurers. The Pharmacy Defendants complete the scheme, selling diverted international FreeStyle test strips to U.S. consumers whose test strip prescriptions are covered by a prescription benefit. This prescription benefit covers the test strips’ full retail price—minus any copayment by the consumer. The prescription benefit reimbursements then being paid by the insurance companies are significantly higher than what Defendants actually paid for the diverted international product. Defendants are reaping significant profits as a result.

8. By diverting FreeStyle test strips meant for international sale, Defendants receive *both* lower-priced product *and* improper full-price U.S. reimbursements from insurers for

selling FreeStyle test strips that do not qualify for those reimbursements. Defendants' sales of diverted FreeStyle test strips do not qualify for the full U.S.-price prescription-benefit reimbursements obtained from the insurers because those reimbursements cover only retail U.S. FreeStyle test strips sold to consumers with a prescription, and not FreeStyle test strips diverted from international markets.

9. Defendants are accomplishing this fraud by submitting falsified reimbursement claims to insurance companies and knowingly causing falsified rebate claims to be submitted to Abbott. This boosts their profits at Abbott's loss. But Abbott and the insurance companies are not the only victims of Defendants' conspiracy.

10. Most troubling, Defendants' victims include the unsuspecting U.S. consumers who are purchasing diverted international FreeStyle test strips.

11. FreeStyle test strips intended for sale outside the United States, while functionally the same as FreeStyle test strips packaged and cleared for sale in the United States, are in fact not authorized for sale in the United States by the Food and Drug Administration ("FDA"). Diverted international test strips are not labeled to meet the FDA's requirements and are not sold by Abbott to U.S. customers. Moreover, every box of retail FreeStyle test strips packaged for retail sale in the United States bear a specific National Drug Code ("NDC") number, 99073-0708-22. The NDC number is required for reimbursement. Diverted international FreeStyle test strips do not have an NDC number and are not eligible for reimbursement in the United States.

12. There are numerous material differences in package labeling and instructions for use between U.S. FreeStyle test strips and diverted international FreeStyle test strips. These differences include:

- Every retail box of U.S. FreeStyle test strips has an NDC number. Boxes

of FreeStyle test strips packaged for sale outside the United States do not have an NDC number and are not eligible for marketing, promotional, reimbursement, or rebate advantages offered by Abbott or third-party payors in the United States.

- The instructional inserts for U.S. FreeStyle test strips and international FreeStyle test strips provide conflicting instructions as to where on the body a blood sample can be taken to perform a blood glucose test. U.S. FreeStyle test strips are cleared by the FDA for testing at only three test sites: finger; upper arm; and palm. Diverted international FreeStyle test strips are approved for testing at a broader range of sites, including the back of hand, forearm, calf, and thigh.
- Every box of U.S. FreeStyle test strips provides a U.S. toll-free customer care phone number. Diverted international FreeStyle test strips do not provide the U.S. toll-free number and instead have international numbers that are not generally accessible from the United States.
- U.S. FreeStyle test strips are accompanied by instructions written in English and Spanish. Several FreeStyle test strips that are packaged for international sale do not include English or Spanish instructions; others include additional foreign languages.
- The handling and use instructions for diverted international FreeStyle test strips utilize units of measurement that are not used in U.S. FreeStyle test strips instructions.
- The outer package labeling for U.S. and international FreeStyle test strips state the range of temperatures in which they can be safely stored. However, temperatures on the outside product packaging for diverted international FreeStyle test strips are displayed in degrees Centigrade, whereas the outside product packaging for U.S. FreeStyle test strips display degrees Fahrenheit and Centigrade.
- Packaging for diverted international FreeStyle test strips contains various symbols that are unfamiliar to U.S. consumers. The symbols are not present on U.S. retail FreeStyle test strip packaging and are prohibited by the FDA for use on in-home consumer-use packaging.
- The outer package label of U.S. FreeStyle test strips provides several FDA-required written warnings and instructions, including “Do not reuse” and “For *in vitro* diagnostic use”. The outer package label of international FreeStyle test strips does not provide these written warnings.

13. These material differences render diverted international FreeStyle test strips misbranded and confusing. Some of them also raise potential health and safety concerns

for diabetic users of FreeStyle test strips. And because the packaging of international FreeStyle test strips is not cleared by the FDA and includes instructions that have been specifically rejected by the FDA, sale of diverted international FreeStyle test strips can constitute a felony.¹

14. Abbott takes great care to ensure that U.S. FreeStyle test strips are shipped to wholesalers and distributors under certain conditions designed to maintain the safety and integrity of the products. With diverted international FreeStyle test strips, like the ones sold by Defendants, Abbott has no assurance that such products are shipped and handled under optimum conditions.

15. Defendants' unauthorized importation and subsequent distribution causes, or is likely to cause, consumer confusion, mistake, and deception to the detriment of Abbott, as well as to the detriment of consumers, insurance companies, third-party payors, and Medicaid and Medicare. As a result of Abbott's extensive branding, marketing, sales, and quality control efforts in the United States and around the world, patients in the United States expect a certain quality, packaging, and overall image from Abbott for FreeStyle test strips. When such patients encounter the diverted international FreeStyle test strips, which bear certain of Abbott's trademarks but which are materially different from what U.S. patients expect, they are likely to be confused and, indeed, disappointed. In addition, because Abbott's products are crucial to the health and well-being of the diabetic patients who rely on FreeStyle test strips for blood glucose testing, the material differences between diverted international FreeStyle test strips and U.S. FreeStyle test strips may pose risks to the unknowing and unsuspecting purchasers of diverted

¹ A medical device is "misbranded" if it is "false or misleading in any particular" or if its labeling does not offer "adequate directions for use." 21 U.S.C. § 352(a), (f). The sale of misbranded medical devices in the United States is a criminal offense under the Federal Food, Drug and Cosmetics Act. 21 U.S.C. §§ 331, 333, 352. Where, as here, the sale is done with an intent to defraud or mislead, the offense is punishable by up to three years' imprisonment. 21 U.S.C. § 331, 333. Also, as discussed below, the Defendants' actions constitute mail and wire fraud. 18 U.S.C. § 1343, 1341.

international FreeStyle test strips. And sales of diverted international FreeStyle test strips cause great damage to Abbott and the goodwill of Abbott's valuable trademarks.

16. As a result of their pattern of illegal acts, and as set forth further below, Defendants are liable to Abbott not only for fraud, trademark infringement, and other common law claims, but also under the federal Racketeering Influenced and Corrupt Organizations Act ("RICO").

PARTIES

Plaintiffs

17. Plaintiff Abbott Laboratories is a publicly-traded global healthcare company with a market value in excess of \$60 billion and is organized under the laws of the State of Illinois, with its principal place of business at Abbott Park, Illinois. Abbott Laboratories is engaged in the business of manufacturing and marketing health care products.

18. Plaintiff Abbott Diabetes Care Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at Alameda, California. Abbott Diabetes Care Inc. is a wholly-owned operating subsidiary of Abbott Laboratories. Abbott Diabetes Care Inc. is engaged in the business of developing and selling blood glucose monitoring systems, including blood glucose test strips.

19. Plaintiff Abbott Diabetes Care Sales Corporation is a corporation organized under the laws of the State of Delaware, with its principal place of business at Alameda, California. Abbott Diabetes Care Sales Corporation is a wholly-owned operating subsidiary of Abbott Diabetes Care Inc. and is engaged in the business of marketing and selling blood glucose monitoring systems, including blood glucose test strips, in the United States.

Distributor Defendants

20. Defendant Adelphia Supply USA ("Adelphia"), formerly d/b/a Adelphia

Supplies, Inc., is, upon information and belief, a corporation organized under the laws of the State of New York, with a principal place of business at 4111 Fort Hamilton Parkway, Brooklyn, New York 11219. Upon information and belief, Adelphia also operates out of an adjacent address, at 4109 Fort Hamilton Parkway, Brooklyn, New York 11219.

21. Defendant Yudah Neuman a/k/a Lenny Neuman, upon information and belief, owns and operates Adelphia. Yudah Neuman resides at 727 East 3rd Street, Unit 1, Brooklyn, New York 11218, with a principal place of business at 4111 Fort Hamilton Parkway, Brooklyn, New York 11219. Defendant Yudah Neuman exercises control over Adelphia and is a moving, conscious, active force behind Adelphia's unlawful conduct.

22. Defendant Reuven Sobel a/k/a Chaim Sobel is, upon information and belief, a principal and chief executive officer of Adelphia. Sobel resides at 1251 47th Street, Apt. 1, Brooklyn, New York 11219, with a principal place of business at 4111 Fort Hamilton Parkway, Brooklyn, New York 11219. Defendant Reuven Sobel exercises control over Adelphia and is a moving, conscious, active force behind Adelphia's unlawful conduct.

23. Defendant Moses Neuman is, upon information and belief, an officer or agent of Adelphia. Moses Neuman resides at 1181 44th Street, Brooklyn, New York 11219, with a principal place of business at 4111 Fort Hamilton Parkway, Brooklyn, New York 11219. Defendant Moses Neuman exercises control over Adelphia and is a moving, conscious, active force behind Adelphia's unlawful conduct.

24. Defendant Shmuel Lezell is, upon information and belief, an officer of Adelphia. Lezell resides at 1365 Carroll Street, Apt. 1C, Brooklyn, New York 11213, with a principal place of business at 4111 Fort Hamilton Parkway, Brooklyn, New York 11219. Defendant Shmuel Lezell exercises control over Adelphia and is a moving, conscious, active force behind Adelphia's unlawful conduct.

25. Defendant Save Rite Medical.com LLC (“Save Rite”) is, upon information and belief, a corporation organized under the laws of the State of New York, with a principal place of business at 694 Myrtle Avenue, Suite 145, Brooklyn, New York 11205.

26. Defendant Marc Kaplan is, upon information and belief, a principal and chief executive officer of Save Rite. Kaplan resides at 168 10th Street, Brooklyn, New York 11215, with a principal place of business at 694 Myrtle Avenue, Suite 145, Brooklyn, New York 11250. Defendant Marc Kaplan exercises control over Save Rite and is a moving, conscious, active force behind Save Rite’s unlawful conduct.

27. Defendant Matrix Distributors, Inc. (“Matrix”) is, upon information and belief, a corporation organized under the laws of the State of New Jersey, with a principal place of business at 110 Tices Lane, Building A, Unit 5B, East Brunswick, New Jersey 08816. Matrix distributes and sells diverted international FreeStyle test strips to residents of New Jersey.

28. Defendant Christopher Benevent is, upon information and belief, president, general director, and director of Matrix. Benevent resides at 430 East 65th Street, Apt. 3L, New York, New York 10065, with a principal place of business at 110 Tices Lane, Building A, Unit 5B, East Brunswick, New Jersey 08816. Defendant Christopher Benevent exercises control over Matrix and is a moving, conscious, active force behind Matrix’s unlawful conduct.

29. Defendant Seth Grumet is, upon information and belief, a general partner, director, and president of Matrix. Seth Grumet resides at 1 Kings Court, Marlboro, New Jersey 07746, with a principal place of business at 110 Tices Lane, Building A, Unit 5B, East Brunswick, New Jersey 08816. Defendant Seth Grumet exercises control over Matrix and is a moving, conscious, active force behind Matrix’s unlawful conduct.

30. Defendant H&H Wholesale Services, Inc. (“H&H”) is, upon information and belief, a corporation organized under the laws of the State of Michigan, with a principal

place of business at 1099 Rochester Road, Troy, Michigan 48083.

31. Defendant Howard Goldman is, upon information and belief, the owner of H&H. Howard Goldman resides at 2590 Kent Ridge Court, Bloomfield Hills, Michigan 48301, with a principal place of business at 1099 Rochester Road, Troy, Michigan 48083. Defendant Howard Goldman exercises control over H&H and is a moving, conscious, active force behind H&H's unlawful conduct.

32. Defendant Lori Goldman is, upon information and belief, the marketing manager of H&H and the spouse of Defendant Howard Goldman. Defendant Lori Goldman resides at 2590 Kent Ridge Court, Bloomfield Hills, Michigan 48301, with a principal place of business at 1099 Rochester Road, Troy, Michigan 48083. Defendant Lori Goldman exercises control over H&H and is a moving, conscious, active force behind H&H's unlawful conduct.

33. Defendant Papoutsanis USA, LLC ("Papoutsanis USA") d/b/a VIP International – Drogaris ("VIP International") is a limited liability corporation organized under the laws of Florida with principal places of business at 15155 Michelangelo Boulevard #305, Delray Beach, Florida 33446 and 1796 Clove Road, Staten Island, New York 10304. VIP International/Drogaris, Inc. was a corporation formerly registered under the laws of the State of New York, with a principal place of business at 1874 Clove Road, Staten Island, New York, 10304.

34. Defendant George Drogaris is, upon information and belief, the owner and president of VIP International. He resides and has a principal place of business at 15155 Michelangelo Boulevard #305, Delray Beach, Florida 33446. Defendant George Drogaris exercises control over VIP International and is a moving, conscious, active force behind VIP International's unlawful conduct.

35. Defendant OSD Capital, Inc. ("OSD Capital"), formerly known as Farnes

Enterprises Corporation (“Farnes”), is, upon information and belief, a corporation organized under the laws of the State of Utah with a principal place of business at 9883 South 500 West, Sandy, Utah 84041.

36. Defendant Overstockdrugstore.com LLC (“Overstockdrugstore.com”) is, upon information and belief, a corporation organized under the laws of the State of Utah with a principal place of business at 14832 S. Concorde Park Drive, Riverton, Utah 84065. Overstockdrugstore.com conducts business under the name SimpleMed Supply (collectively, with Overstockdrugstore.com, “SimpleMed”), which is an active “DBA” (Doing Business As) entity in Utah.

37. Defendant Rick Evenson is, upon information and belief, the chief executive officer of SimpleMed. Rick Evenson resides at 1739 East Horizon Point Circle, Draper, Utah 84020 with a principal place of business at 14832 S. Concorde Park Drive, Riverton, Utah 84065. Defendant Rick Evenson exercises control over SimpleMed and is a moving, conscious, active force behind SimpleMed’s unlawful conduct.

38. Defendant Kevin Plumb is, upon information and belief, the manager of Defendant Overstockdrugstore.com. Plumb resides at 3 East Falconwood Lane, Sandy, Utah 84092 with a principal place of business at 14832 S. Concorde Park Drive, Riverton, Utah 84065. Defendant Kevin Plumb exercises control over SimpleMed and is a moving, conscious, active force behind SimpleMed’s unlawful conduct.

39. Defendant Budget Health Corporation d/b/a Budget Drugs Pharmacy (“Budget Drugs”) is, upon information and belief, a corporation organized under the laws of the State of Florida with a principal place of business at 2500 East Hallandale Beach Boulevard, Suite P, Hallandale Beach, Florida 33009.

40. Defendant John Fandetti is, upon information and belief, an officer for

Budget Drugs. John Fandetti resides at 2301 Bellevue Court, Hoover, Alabama 35226 with a principal place of business at 2500 East Hallandale Beach Boulevard, Suite P, Hallandale Beach, Florida 33009. Defendant John Fandetti exercises control over Budget Drugs and is a moving, conscious, active force behind Budget Drugs' unlawful conduct.

41. Defendant Robert Newmyer, upon information and belief, is an officer for Budget Drugs. Newmyer resides at 740 SW 4th Street, Hallandale Beach, Florida 33009 with a principal place of business at 2500 East Hallandale Beach Boulevard, Suite P, Hallandale Beach, Florida 33009. Defendant Robert Newmyer exercises control over Budget Drugs and is a moving, conscious, active force behind Budget Drugs' unlawful conduct.

42. Defendant Maria Fandetti, upon information and belief, is an officer for Budget Drugs. Maria Fandetti resides at 2301 Bellevue Court, Hoover, Alabama 35226 with a principal place of business at 2500 East Hallandale Beach Boulevard, Suite P, Hallandale Beach, Florida 33009. Defendant Maria Fandetti exercises control over Budget Drugs and is a moving, conscious, active force behind Budget Drugs' unlawful conduct.

43. Defendant Lori Blue, upon information and belief, is an officer for Budget Drugs. Blue resides at 1135 Scarlet Oak Street, Hollywood, Florida 33019 with a principal place of business at 2500 East Hallandale Beach Boulevard, Suite P, Hallandale Beach, Florida 33009. Defendant Lori Blue exercises control over Budget Drugs and is a moving, conscious, active force behind Budget Drugs' unlawful conduct.

44. Defendant Anthony Meola, upon information and belief, is an officer for Budget Drugs. Meola resides at 7641 NW 13th Court, Plantation, Florida 33322 with a principal place of business at 2500 East Hallandale Beach Boulevard, Suite P, Hallandale Beach, Florida 33009. Defendant Anthony Meola exercises control over Budget Drugs and is a moving, conscious, active force behind Budget Drugs' unlawful conduct.

45. Defendant Mark D. Henkin (“Mark Henkin”), upon information and belief, is an officer for Budget Drugs. Mark Henkin resides at 2454 Andros Lane, Fort Lauderdale, Florida 33312 with a principal place of business at 2500 East Hallandale Beach Boulevard, Suite P, Hallandale Beach, Florida 33009. Defendant Mark Henkin exercises control over Budget Drugs and is a moving, conscious, active force behind Budget Drugs’ unlawful conduct.

46. Defendant Dream Cereal Inc. d/b/a Diabetessupplies4less.com (“Diabetes Supplies 4 Less”) is, upon information and belief, a corporation organized under the laws of the State of Florida with a principal place of business at 562 East Woolbright Road, Suite 202, Boynton Beach, Florida 33435.

47. Defendant Douglas Hauck is, upon information and belief, Diabetes Supplies 4 Less’s president. Hauck resides at 125 Marlin Drive, Boynton Beach, FL 33435. Defendant Douglas Hauck exercises control over Diabetes Supplies 4 Less and is a moving, conscious, active force behind Diabetes Supplies 4 Less’s unlawful conduct.

Pharmacy Defendants

48. Defendant Berkeley Drugs Inc. (“Berkeley Drugs”) is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business at 1951 Flatbush Avenue, Brooklyn, New York 11234.

49. Defendant Majid Hameed is, upon information and belief, the chief executive officer of Berkeley Drugs. Hameed resides at 84 Old Brook Road, Dix Hills, New York 11746 with a principal place of business at 1951 Flatbush Avenue, Brooklyn, New York 11234. Defendant Majid Hameed exercises control over Berkeley Drugs and is a moving, conscious, active force behind Berkeley Drugs’ unlawful conduct.

50. Defendant Eugene Ha is, upon information and belief, the supervisor of

Berkeley Drugs. Ha resides at 20 Merrivale Road, Great Neck, New York 11020 with a principal place of business at 1951 Flatbush Avenue, Brooklyn, New York 11234. Defendant Eugene Ha exercises control over Berkeley Drugs and is a moving, conscious, active force behind Berkeley Drugs' unlawful conduct.

51. Defendant Careway Pharmacy Inc. ("Careway Pharmacy") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business of 1174 Flatbush Avenue, Brooklyn, New York 11226.

52. Defendant Anatoliy Fain is, upon information and belief, the supervisor of Careway Pharmacy. Fain resides at 13523 82nd Avenue, Unit PH2, Jamaica, New York 11435, with a principal place of business at 1174 Flatbush Avenue, Brooklyn, New York 11226. Defendant Anatoliy Fain exercises control over Careway Pharmacy and is a moving, conscious, active force behind Careway Pharmacy's unlawful conduct.

53. Defendant Harrico-Galler Drug Corporation ("Harrico-Galler") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business of 1409 Coney Island Avenue, Brooklyn, New York 11230.

54. Defendant John Gallagher is, upon information and belief, the chief executive officer of Harrico-Galler. Gallagher resides at 460 Beach 134th Street, Rockaway Park, New York 11694 with a principal place of business of 1409 Coney Island Avenue, Brooklyn, New York 11230. Defendant John Gallagher exercises control over Harrico-Galler and is a moving, conscious, active force behind Harrico-Galler's unlawful conduct.

55. Defendant Haber J&N Inc. d/b/a The Modern Chemist ("The Modern Chemist") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business of 1630 Coney Island Avenue, Brooklyn, New York 11230.

56. Defendant Naomi Haber is, upon information and belief, the chief executive officer of The Modern Chemist. Naomi Haber resides at 3067 Bedford Avenue, Brooklyn, New York 11210 with a principal place of business of 1630 Coney Island Avenue, Brooklyn, New York 11230. Defendant Naomi Haber exercises control over The Modern Chemist and is a moving, conscious, active force behind The Modern Chemist's unlawful conduct.

57. Defendant Jerry Haber is, upon information and belief, the supervisor of the pharmacy at The Modern Chemist. Jerry Haber resides at 3067 Bedford Avenue, Brooklyn, New York 11210 with a principal place of business of 1630 Coney Island Avenue, Brooklyn, New York 11230. Defendant Jerry Haber exercises control over The Modern Chemist and is a moving, conscious, active force behind The Modern Chemist's unlawful conduct.

58. Defendant Norstrand Pharmacy, LLC d/b/a Vanderveer Pharmacy ("Vanderveer Pharmacy") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business at 1887 Nostrand Avenue, Brooklyn, NY 11226. Vanderveer Pharmacy's address for service of process is 201 Bennington Terrace, Paramus, New Jersey 07652.

59. Defendant Sarathchandra Adusumalli is, upon information and belief, the supervisor of Vanderveer Pharmacy. Adusumalli resides at 3023 Edward Stec Boulevard, Edison, New Jersey 08837 with a principal place of business of 1887 Nostrand Avenue, Brooklyn, NY 11226. Defendant Sarathchandra Adusumalli exercises control over Vanderveer Pharmacy and is a moving, conscious, active force behind Vanderveer Pharmacy's unlawful conduct.

60. Defendant Hemagiri Gayam is, upon information and belief, the registered agent of Vanderveer Pharmacy. Gayam resides at 201 Bennington Terrace, Paramus, New

Jersey 07652 with a principal place of business of 201 Bennington Terrace, Paramus, New Jersey 07652. Defendant Hemagiri Gayam exercises control over Vanderveer Pharmacy and is a moving, conscious, active force behind Vanderveer Pharmacy's unlawful conduct.

61. Defendant Lev RX Corp. d/b/a Kira's Pharmacy ("Kira's Pharmacy"), is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business at 88 Kings Highway, Brooklyn, New York 11214.

62. Defendant Kira Levkouskaya is, upon information and belief, the Chief Executive Officer of Kira's Pharmacy. Levkouskaya resides at 3535 Emmons Avenue, Apartment 611, Brooklyn, NY 11235. Defendant Kira Levkouskaya exercises control over Kira's Pharmacy and is a moving, conscious, active force behind Kira's Pharmacy's unlawful conduct.

63. Defendant Eliyahus Pharmacy, Inc. ("Eliyahus Pharmacy") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business at 573 Kings Highway, Brooklyn, New York 11223.

64. Defendant Ilias Mlabasati is, upon information and belief, the Chief Executive Officer of Eliyahus Pharmacy. Mlabasati resides at 2120 Ocean Parkway, Brooklyn, New York 11223. Defendant Ilias Mlabasati exercises control over Eliyahus Pharmacy and is a moving, conscious, active force behind Eliyahus Pharmacy's unlawful conduct.

65. Defendant Global Care Pharmacy, Inc. ("Global Care Pharmacy") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business at 5905 8th Avenue, Brooklyn, New York 11220.

66. Defendant D.K.Y. Enterprises, Inc. d/b/a 8th Avenue Pharmacy ("8th Avenue Pharmacy") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business at 5504 8th Avenue, Brooklyn, New

York 11220.

67. Defendant Kim Ping Jim is, upon information and belief, the Chief Executive Officer of 8th Avenue Pharmacy. Jim resides at 4825 190th Street, Fresh Meadows, New York 11365. Defendant Kim Ping Jim exercises control over 8th Avenue Pharmacy and is a moving, conscious, active force behind 8th Avenue Pharmacy's unlawful conduct.

68. Defendant TGIS Pharmacy, Inc. d/b/a Sunrise Family Pharmacy ("Sunrise") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business at 6324 4th Avenue, Brooklyn, New York 11220.

69. Defendant Sajid Javed is, upon information and belief, the chief executive officer of Sunrise. Javed resides at 6981 180th Street, Fresh Meadows, New York 11365. Defendant Sajid Javed exercises control over Sunrise and is a moving, conscious, active force behind Sunrise's unlawful conduct.

70. Defendant Bay Pharmacy Inc. ("Bay Pharmacy") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business at 2240 86th Street, Brooklyn, New York 11214.

71. Defendant Irene Piker is, upon information and belief, the chief executive officer of Bay Pharmacy. Piker resides at 4924 Ocean Avenue, Brooklyn, New York 11235. Defendant Irene Piker exercises control over Bay Pharmacy and is a moving, conscious, active force behind Bay Pharmacy's unlawful conduct.

72. Defendant B & T Marlboro Pharmacy, Inc. ("B & T Marlboro Pharmacy") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business at 2845 86th Street, Brooklyn, New York 11223.

73. Defendant Anatoly Gorokhovsky is, upon information and belief, the chief executive officer of B & T Marlboro Pharmacy. Gorokhovsky resides at 35 Seacoast Terrace,

Apartment 16D, Brooklyn, New York 11235. Defendant Anatoly Gorokhovsky exercises control over B & T Marlboro Pharmacy and is a moving, conscious, active force behind B & T Marlboro Pharmacy's unlawful conduct.

74. Defendant Larke Drugs, Inc. d/b/a 110 Pharmacy & Surgical ("110 Pharmacy & Surgical") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business at 459 Walt Whitman Road, Melville, New York 11747.

75. Defendant Prasad Venigalla is, upon information and belief, the chief executive officer of 110 Pharmacy & Surgical. Venigalla resides at 5 Evergreen Way, Glen Head, New York 11545. Defendant Prasad Venigalla exercises control over 110 Pharmacy & Surgical and is a moving, conscious, active force behind 110 Pharmacy & Surgical's unlawful conduct.

76. Defendant La Ruche Pharmacy, Inc. ("La Ruche Pharmacy") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business at 494 Rockaway Parkway, Brooklyn, New York 11212. La Ruche Pharmacy's address for service of process is 847 Annandale Road, Staten Island, New York 10312.

77. Defendant Sunil B. Patel is, upon information and belief, the chief executive officer of La Ruche Pharmacy. Patel resides at 14 Anthony Avenue, Edison, New Jersey 08820. Defendant Sunil B. Patel exercises control over La Ruche Pharmacy and is a moving, conscious, active force behind La Ruche Pharmacy's unlawful conduct.

78. Defendant Estates Pharmacy, Inc. ("Estates Pharmacy") is, upon information and belief, a corporation organized under the laws of the State of New York with a principal place of business and address for service of process at 169-01 Hillside Avenue,

Jamaica, New York 11432.

79. Defendant Mohammed Nuruddin is, upon information and belief, the chief executive officer of Estates Pharmacy. Nuruddin resides at 8220 210th Street, Queens Village, New York 11432. Defendant Mohammed Nuruddin exercises control over Estates Pharmacy and is a moving, conscious, active force behind Estates Pharmacy's unlawful conduct.

John Doe Defendants

80. Defendants John Does 1-10 are other persons and entities that are involved in the conspiracy to import, distribute, and sell diverted international FreeStyle test strips but whose identities are presently unknown.

JURISDICTION AND VENUE

81. The Court has subject matter jurisdiction over this action under Section 39 of the Trademark Act of 1946 (the "Lanham Act"), 15 U.S.C. § 1121; 28 U.S.C. §§ 1331, 1332, 1338(a), 1338(b), and 1367; 18 U.S.C. §§ 1964 and 1965; and general principles of ancillary and pendent jurisdiction.

82. The amount of damages at issue exceeds \$75,000, exclusive of interest and costs.

83. The Court has personal jurisdiction over the Defendants because they regularly transact or have transacted business in the Eastern District of New York by, for example, selling Abbott FreeStyle blood glucose test strips and other manufacturers' products into the state of New York and receiving insurance reimbursements from insurance companies located in the state of New York.

84. Venue is proper in the Eastern District of New York pursuant to 28 U.S.C. § 1391(b) and (c) in that a substantial part of the events or omissions giving rise to the claim occurred in this district, and one or more of the Defendants is subject to personal jurisdiction in

this district.

FACTS

85. Abbott sells the well-known, high-quality FreeStyle blood glucose monitoring systems, which includes FreeStyle test strips. Abbott markets and sells FreeStyle test strips throughout the world, and is viewed as a dependable source of high-quality and reliable test strips.

86. Diabetes is a group of diseases characterized by high blood glucose levels that result from defects in the body's ability to produce and/or use insulin. According to the American Diabetes Association, diabetes affects more than 25 million Americans. Diabetes is a chronic disease that must be managed closely to avoid the risk of serious illness, complications, and even death.

87. Millions of people who have been diagnosed with diabetes depend on Abbott's FreeStyle test strips every day to monitor their blood sugar to enable them to regulate their diet and medication.

88. Diabetes patients use FreeStyle test strips by first placing a test strip into a compatible FreeStyle meter. The patient then obtains a tiny blood sample from an indicated "test site"—which in the United States is the patient's fingertip, upper arm, or palm—using a lancing device. Next, the patient applies the blood sample to the test strip. The test result, or blood glucose reading, is displayed on the meter's digital screen seconds later. Based on this reading, the patient makes decisions concerning when to take insulin and how to adjust his or her diet to ensure a healthy blood-glucose level.

Abbott's Trademarks

89. Abbott Laboratories and Abbott Diabetes Care Inc. are the owners of a family of U.S. trademarks including, among others, the following trademarks that appear on all

packaging for FreeStyle® and FreeStyle Lite® blood glucose test strips (collectively referred to herein as the “FreeStyle Marks”).

- Abbott Diabetes Care Inc.’s “FREESTYLE” trademark was registered on the Principal Register of the United States Patent and Trademark Office on July 4, 2006, as U.S. Registration No. 3,111,863, and was recognized by the Patent and Trademark Office (“PTO”) as incontestable under 15 U.S.C. § 1065 on June 28, 2012;
- Abbott Diabetes Care Inc.’s “FREESTYLE LITE” trademark was registered on the Principal Register of the United States Patent Office on August 19, 2008, as U.S. Registration No. 3,488,499, and was recognized by the PTO as incontestable under 15 U.S.C. § 1065 on May 31, 2014;



- Abbott Diabetes Care Inc.’s trademark, which consists of a butterfly with a silver body, black wings, yellow and orange oblong shapes on the wings with two rows of white spots going around the oblong shapes, and with blue shading, was registered on the Principal Register of the United States Patent Office on September 18, 2012, as U.S. Registration No. 4,210,535;
- Abbott Laboratories’ “ABBOTT” trademark was registered on the Principal Register of the United States Patent Office on December 15, 2009, as U.S. Registration No. 3,724,557;
- Abbott Laboratories’ “ABBOTT” trademark was registered on the Principal Register of the United States Patent Office on August 31, 2010, as U.S. Registration No. 3,842,268;
- Abbott Laboratories’ “ABBOTT” trademark was registered on the Principal Register of the United States Patent Office on August 31, 2010, as U.S. Registration No. 3,842,269;
- Abbott Laboratories’ “ABBOTT” trademark was registered on the Principal Register of the United States Patent Office on September 6, 2011, as U.S. Registration No. 4,023,123; and



- Abbott Laboratories’ trademark service mark was registered on the Principal Register of the United States Patent Office on June 6, 1989, as U.S. Registration No. 1,542,129 and was recognized by the PTO as incontestable under 15 U.S.C. § 1065 on January 5, 1996.

90. The sale of FreeStyle test strips has been tremendously successful in part due to Abbott's marketing and promotion of the FreeStyle brand throughout the country.

91. Abbott distributes over 600 million test strips every year in the United States alone and has sold billions of FreeStyle test strips for over \$1 billion dollars in the United States over the past five years.

92. The FreeStyle brand is recognized in the United States and throughout the world as a high-quality, reliable blood glucose test strip manufactured and distributed by Abbott. FreeStyle test strips are sold in pharmacies throughout the United States and world.

93. As a result of Abbott's extensive advertising and promotion of FreeStyle test strips in connection with the FreeStyle Marks, Abbott's widespread and long-running sale of FreeStyle test strips, and the celebrity that the FreeStyle Marks have achieved, blood glucose test strips bearing FreeStyle Marks have been and are now recognized by the consuming public in the United States and in the trade as originating from a single source: Abbott.

94. Test strips bearing the FreeStyle Marks have come to be known by the purchasing public throughout the United States and abroad as blood glucose test strips of the highest quality. As a result, the FreeStyle Marks and the goodwill associated with them are of inestimable value to Abbott.

95. Abbott has used and is currently using the FreeStyle Marks in commerce and in connection with its sale of FreeStyle test strips, and plans to continue such use in the future.

Material Differences Between U.S. and International FreeStyle Test Strips

96. As is the case with many products, particularly those related to health and safety, the package labeling and indications for use of FreeStyle test strips Abbott packages for retail sale in the United States differ in significant and material ways from the package labeling

and indications for use of FreeStyle test strips Abbott packages for retail sale outside the United States.

97. Public health agencies in the United States and abroad actively regulate the sale of blood glucose test strips, and in particular, what must be included and excluded from their labels and packaging. Different countries, however, have different regulatory requirements. In the United States, the FDA has cleared the package labeling and indications for use of FreeStyle test strips under the FDA's particular, stringent requirements. In contrast, the package labeling and indications for use of international FreeStyle test strips differ from U.S. FreeStyle test strips, and are therefore not cleared or authorized for sale in the United States. These differences are outlined below.

98. **No NDC Number.** As explained above, every box of FreeStyle test strips packaged for retail sale in the United States has a specific NDC number. This number is required for reimbursements and rebates. The NDC number for every retail 50-count box of FreeStyle Lite test strips is 99073-0708-22. This NDC number is located both on the front of every box of FreeStyle test strips intended for retail sale in the United States and in the barcode on the bottom of every box of U.S. FreeStyle test strips, as shown in **Figures 1 and 2** below:

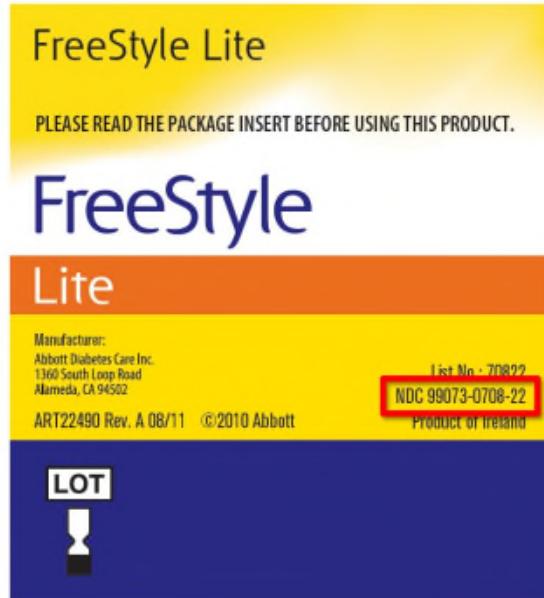


Figure 1



Figure 2

FreeStyle test strips packaged for sale outside the United States do not have an NDC number anywhere on their packaging and are not entitled to reimbursements or rebates in the United States.

99. **Different Indicated Test Sites.** To perform a blood glucose test, the patient must obtain a blood drop from a particular test site on his or her body. Many patients test their glucose levels multiple times per day and would like to be able to use a number of different test sites. Accordingly, in 2009, Abbott sought clearance from the FDA to indicate testing at seven sites: finger; upper arm; palm; back of hand; forearm; calf; and thigh. In support of this

application, Abbott submitted testing date for all seven sites. In evaluating this data, however, the FDA determined that the back of hand, forearm, calf, and thigh test sites did not meet its criteria. The FDA therefore only cleared U.S. FreeStyle test strips to indicate three test sites: finger; upper arm; and palm.

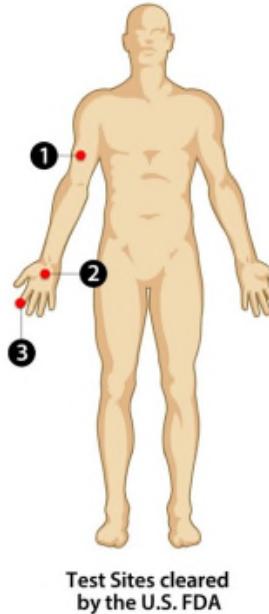


Figure 3

100. Outside the United States, FreeStyle test strips are approved for testing at a broader range of sites, including: back of hand; forearm; calf; and thigh.

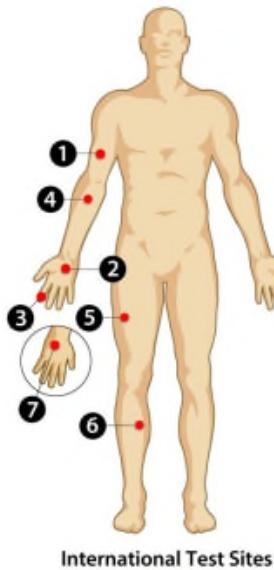


Figure 4

Accordingly, international FreeStyle test strips are packaged with guidance and instructions for testing at a wider range of sites than U.S. FreeStyle test strips.

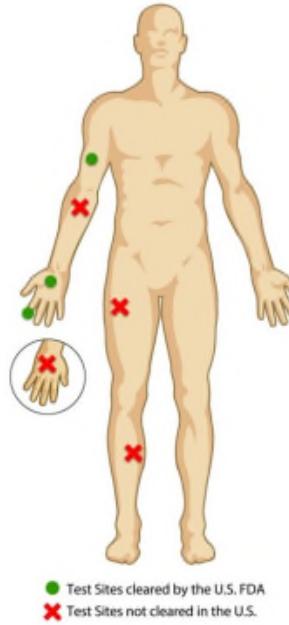


Figure 5

101. **No U.S. Toll-Free Phone Number.** Every box of U.S. FreeStyle test strips provides a U.S. toll-free phone number for U.S. consumers to call with any product-related

questions, concerns, or issues, or to report any adverse events. International FreeStyle test strips do not provide the U.S. toll-free number anywhere in its packaging, and instead have international numbers that are not generally accessible from the United States. These differences are reflected in **Figure 6**:

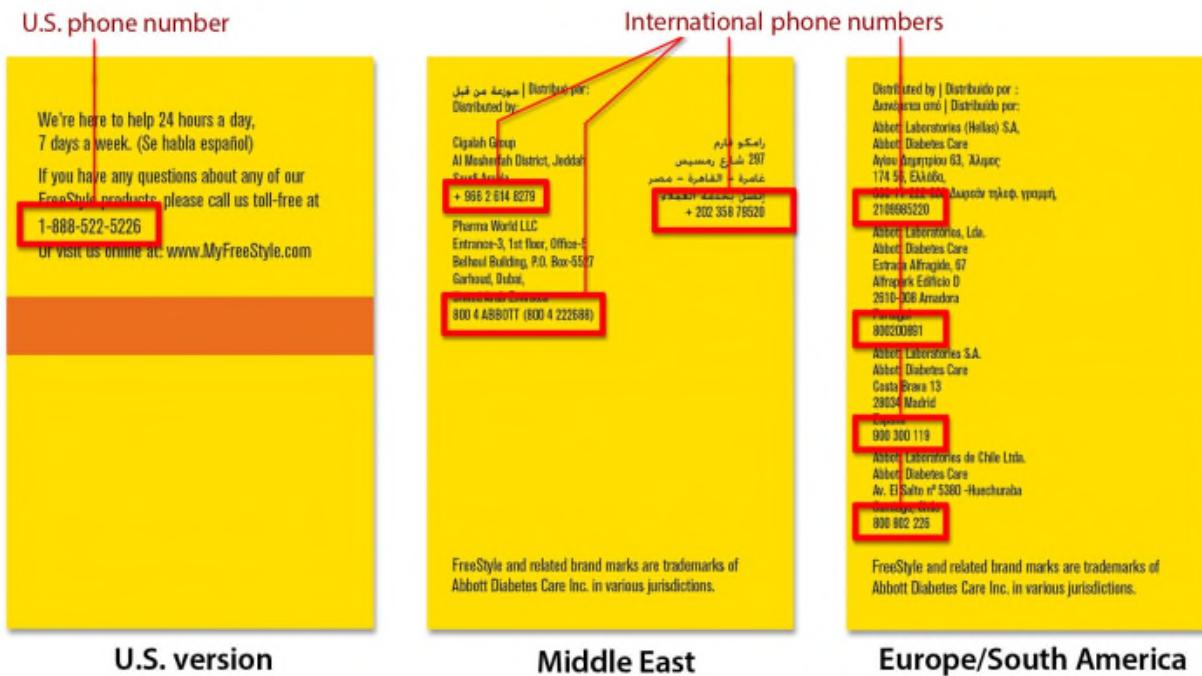


Figure 6

102. **Different Languages.** The packaging of every box of FreeStyle test strips contains very important information concerning usage and handling. Every box of FreeStyle test strips also contains an instructional insert providing a substantial amount of vital information, including directions and warnings for the use of FreeStyle test strips. It is critical that consumers be able to read and understand this information.

103. The language or languages used in the packaging and instructional inserts varies depending on the intended country or region of distribution. The packaging and instructional inserts for all U.S. FreeStyle test strips are in English, as required by the FDA, and Spanish. FreeStyle test strips that are packaged for sale outside the United States do not provide

instructions in English, do not provide instructions in Spanish, or provide languages in addition to English and Spanish. Copies of the exterior labels and instructional inserts for FreeStyle test strips are provided herein as follows: the United States as **Exhibit A**; Canada as **Exhibit B**; Germany, Switzerland, France, Belgium, and the Netherlands as **Exhibit C**; India as **Exhibit D**; the Middle East as **Exhibit E**; the United Kingdom, New Zealand, and Jamaica as **Exhibit F**; and Spain, Portugal, Greece, and South America as **Exhibit G**.

104. **Use of Symbols.** The FDA does not approve the use of symbols on packaging for home-use products unless the symbols are accompanied by adequate explanatory text. The FDA has published guidance instructing manufacturers, including Abbott, not to use symbols for any lay-user products: “FDA does not recognize the symbols for use in the labels and labeling of over-the-counter or prescription home-use [in vitro diagnostic devices (“IVD”)]. Validation data introduced through FDA’s consensus standards recognition process supported the use of symbols for IVD professional labels and labeling, not for consumer labeling.” *See* “Guidance for Industry and FDA Staff: Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use” at Section VI, *available at* <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm085404.htm#6>.

105. International FreeStyle test strips are packaged in boxes that bear various symbols concerning, among other things, the manufacturer, expiration date, and storage temperature limitations:

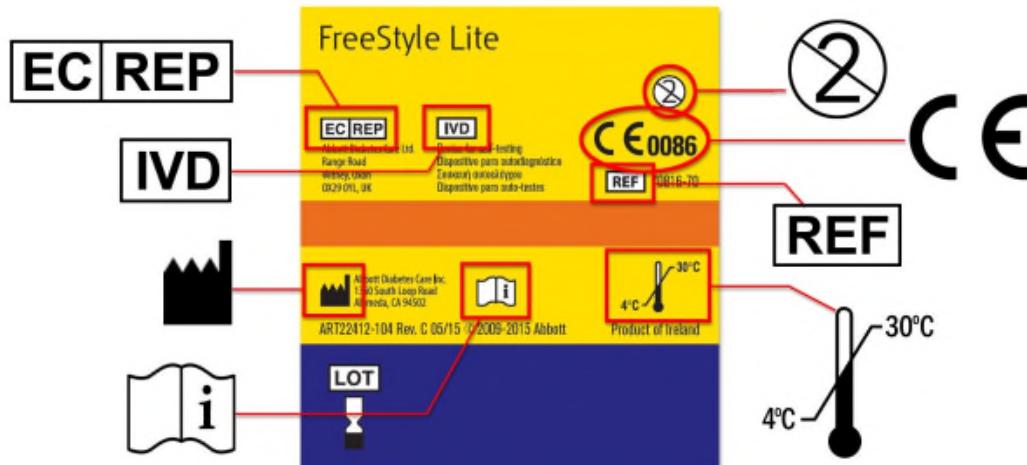


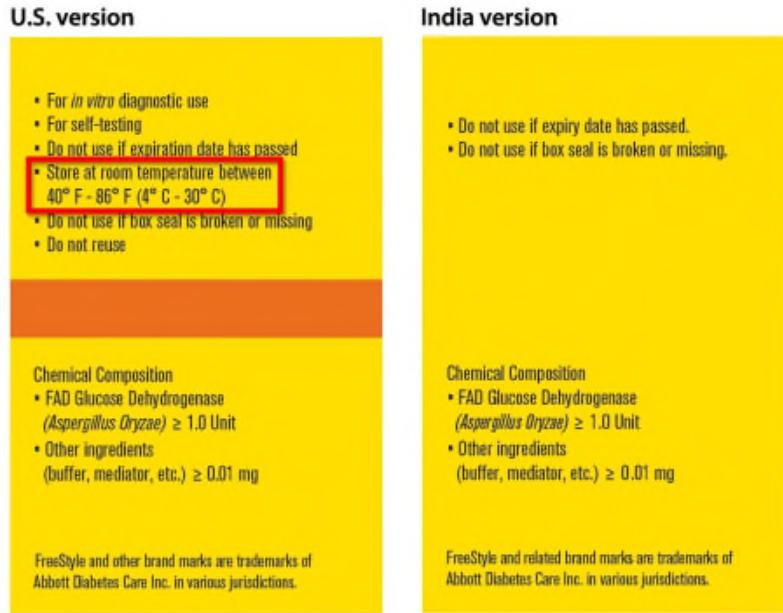
Figure 7

106. U.S. FreeStyle test strips are not packaged in boxes bearing these symbols.

The sale of international FreeStyle test strips in the United States not only violates the FDA's guidance against symbols, but could confuse or fail to inform patients about the proper use of the test strips.

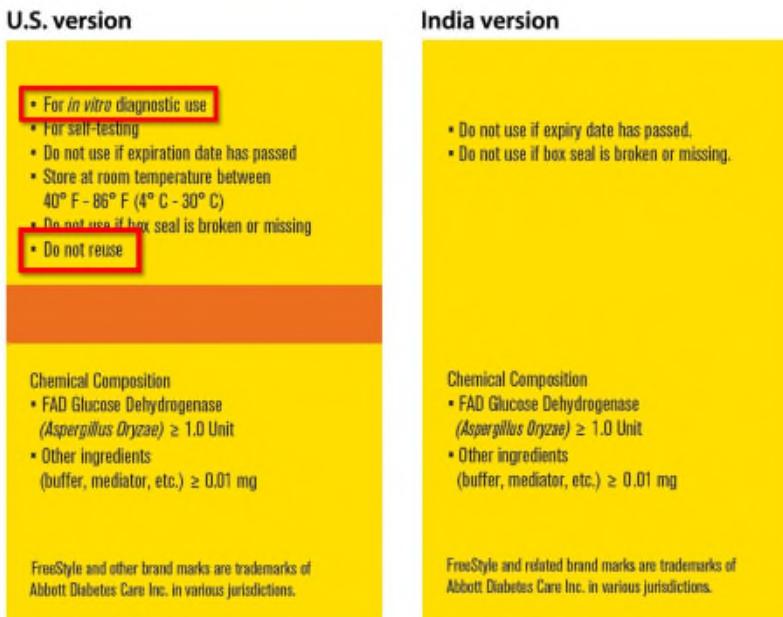
107. **Different Units of Measurement.** The FDA sets restrictions on the units of measurement U.S. product packaging can utilize. The FDA generally requires that products utilize milligrams and deciliters exclusively, and not other units, which can confuse U.S. consumers. However, many regions around the world use other units of measurement, including millimoles. Moreover, the instructional insert for FreeStyle test strips packaged for sale in Canada utilize millimoles exclusively. *See Exhibit B.*

108. **Different Temperature Scales.** The FDA also requires that U.S. products use Fahrenheit as the unit of measurement for temperature. The side of every U.S. box of FreeStyle test strips includes the following warning: "Store at room temperature between 40° F - 86° F (4° C - 30° C)". International FreeStyle test strips do not provide this written warning anywhere on the outer box; instead, they rely on a symbol indicating "4° C" and "30° C" without explanatory text or the Fahrenheit equivalent.

**Figure 8**

109. **Missing Warnings.** The outer package label of every box of U.S.

FreeStyle test strips provides several written warnings and instructions, including “Do not reuse” and “For *in vitro* diagnostic use”. The outer package label of international FreeStyle test strips does not provide these written warnings.

**Figure 9**

110. **Compatible Meters.** The FDA requires that FreeStyle test strips be indicated for use exclusively with FreeStyle, FreeStyle Flash, and FreeStyle Freedom meters; and that FreeStyle Lite test strips be indicated for use exclusively with the FreeStyle Lite and FreeStyle Freedom Lite meters. In other words, the FDA has not cleared FreeStyle test strips to be indicated for use with FreeStyle Lite brand meters; and, alternatively, the FDA has not cleared FreeStyle Lite test strips to be indicated for use with other FreeStyle brand meters. Outside the United States, FreeStyle test strips are approved for use with meters using FreeStyle coulometry technology, regardless of whether the meter is a FreeStyle meter, FreeStyle Lite meter, or another FreeStyle-brand meter. Moreover, unlike U.S. FreeStyle and FreeStyle Lite test strips, international FreeStyle and FreeStyle Lite test strips are also indicated for use with FreeStyle InsuLinx and FreeStyle Navigator meters (to name a few) and are packaged accordingly.



Figure 10

Authorized Distribution of FreeStyle Test Strips in the United States

111. Retail U.S. FreeStyle test strips are designed for sale by U.S. pharmacies. They can be sold to anyone in the United States, including customers covered by a prescription

benefit and customers who would like to pay cash over-the-counter. Abbott wholesales retail boxes of FreeStyle test strips at a set list price throughout the United States. The current list price in the United States for retail 50-count boxes of FreeStyle Lite test strips is \$72.58, or roughly \$1.45 per test strip.

112. Most U.S. consumers—over 95%—purchase FreeStyle test strips with a prescription. Consumers with prescriptions for test strips are typically eligible to receive insurance coverage for their purchase, usually from private insurance or Medicare and Medicaid programs. Insurers provide prescription drug coverage according to a formulary, which is a schedule that lists the prescription drugs and medical devices the insurer will cover and the amount the insurer will reimburse for any particular drug or device. These formularies list the drugs and devices eligible for reimbursement according to NDC number. If a product does not have an NDC number that is listed on the insurer’s formulary, it is not eligible for reimbursement from insurers.

113. When a pharmacy dispenses a box of FreeStyle test strips to a consumer who is using a prescription benefit, it informs the consumer’s insurer of the purchase by scanning the unique U.S. FreeStyle test strips NDC number into the pharmacy computer terminal.

114. NDC numbers are used as a key component of reimbursement systems that enable automated processing of claims. The pharmacy scans the U.S. retail NDC number to submit a claim to the insurer for reimbursement. The insurance claim is processed according to the NDC number. The submission of the NDC number is a representation that the consumer was dispensed the product corresponding to the submitted NDC—that is, a box of FreeStyle test strips intended and authorized for sale in the United States. And based on this representation, the insurer makes a reimbursement payment to the pharmacy. This process is referred to as “adjudication.”

115. Insurers, third-party payors, and other large purchasers negotiate and contract with Abbott concerning how much they will pay—or more precisely, how much they will be rebated—for FreeStyle test strips. Pursuant to these contracts, when a transaction is adjudicated, Abbott also pays a rebate for every box of FreeStyle test strips for which an insurer paid or reimbursed the pharmacy. As Defendants are well aware, Abbott pays substantial rebates to the insurers for reimbursements they pay out on sales of U.S. FreeStyle test strips. Abbott's revenue for the sale of every adjudicated box of U.S. FreeStyle test strips therefore amounts to the list price minus the contractually agreed-upon rebate it pays to the insurer. The U.S. adjudication process, including reimbursement and rebate payment, is illustrated in **Figure 11**:

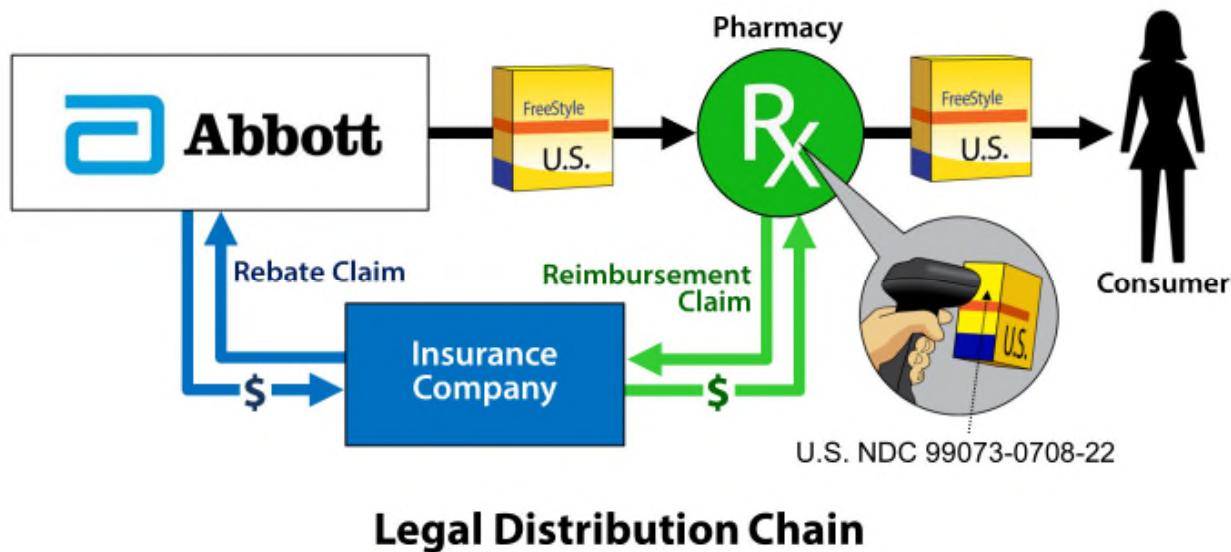


Figure 11

116. Insurers who are covering test strips under a prescription benefit will not pay any reimbursement for the sale of FreeStyle test strips without a valid NDC number. And Abbott will not pay any rebate for the sale of FreeStyle test strips without a valid NDC number. It would be fraudulent for a distributor or retailer of FreeStyle test strips to designate sales of non-U.S. retail FreeStyle test strips in its reimbursement claims to insurance companies by using a U.S. NDC number, and thereby secure the reimbursement paid by the insurers on a U.S. retail

box of FreeStyle test strips. The same actions would amount to a fraud against Abbott, who would be paying rebates secured by the same bait-and-switch. This is exactly what is happening here.

The Mechanics of the Defendants' Fraudulent Scheme

117. The Defendants are participating in a scheme to defraud Abbott by purchasing international FreeStyle test strips, diverting them to the United States, and selling them to U.S. consumers.

118. FreeStyle test strips are manufactured in Ireland with a specific stock keeping unit ("SKU") and lot number. Each lot is only manufactured for sale in a specific country or region. FreeStyle test strips that are manufactured for sale in the United States are assigned different SKU and lot numbers than FreeStyle test strips manufactured for sale outside the United States.

119. Abbott uses the SKU and lot numbers to track where the test strips are shipped and then to monitor them if any safety or quality issues arise.

120. When a recall is warranted, for example, Abbott notifies the regulatory agencies in the countries that were authorized to receive the affected lot number, informing them of the particular issue and seeking their guidance. Abbott then issues a recall notice, which may include a press release and a website posting. For each affected country, Abbott provides a direct notification to all consignees for the affected lot numbers, including distributors, retailers, and pharmacies, notifying them of the issue with the product and what further action is necessary. Where possible, Abbott also directly notifies consumers and health care professionals whose patients have been trained on the recalled product.

121. Recall notices are only sent to countries and/or consumers that are authorized to have received the particular SKU or lot number that is the subject of the recall.

This helps to minimize consumer confusion and unnecessary market disruption; prevent consumers from becoming desensitized to important recall notices as a result of receiving numerous inapplicable notifications; and ensure that consumers do not unnecessarily dispose of their products in instances in which only a specific SKU or lot number is affected.

122. Abbott devotes a substantial amount of effort and resources to ensure product quality and consumer safety. In addition to the pre-market measures Abbott takes, after FreeStyle test strips are distributed, Abbott continues to monitor the market—receiving consumer inquiries, tracking and investigating complaints and market issues, and performing any necessary field actions, including making targeted recalls and initiating legal proceedings. When Abbott discovers product in the United States that is not suitable or approved for sale, Abbott also promptly notifies relevant federal and local law-enforcement authorities.

123. As a result of its market monitoring, Abbott recently discovered Defendants' fraudulent scheme after seeing a substantial increase in the number of diverted international FreeStyle test strips being sold in the United States.

124. In many foreign countries, the list price for FreeStyle test strips is lower than in the United States. This is because the insurance systems in those countries differ from that in the United States. In particular, they involve little or no reimbursements or rebates. After all reimbursements and rebates are considered, the net price for U.S. and foreign FreeStyle test strips is similar throughout the developed world.

125. Because the list price for international FreeStyle test strips is lower than the U.S. list price, Defendants (and others like them) are buying large quantities of international FreeStyle test strips, importing them into the United States, and selling them to U.S. consumers with insurance. They are then submitting these sales to insurers for reimbursement to obtain inflated profits.

126. To receive these reimbursements, Defendants are engaging in fraudulent and criminal conduct. For nearly every sale of diverted international FreeStyle test strips Defendants make to a U.S. consumer, the Pharmacy Defendants are dispensing the test strips pursuant to the consumer's prescription benefit. However, because the box of diverted international FreeStyle test strips does not have an NDC number, the Pharmacy Defendants are scanning in the NDC code from a retail box of U.S. FreeStyle test strips. Thus, while the Pharmacy Defendants are dispensing a box of diverted international FreeStyle test strips (which is ineligible for reimbursements and rebates in the United States), they are fraudulently claiming they sold a box of U.S. FreeStyle test strips with a valid NDC number (which is eligible for reimbursements and rebates).

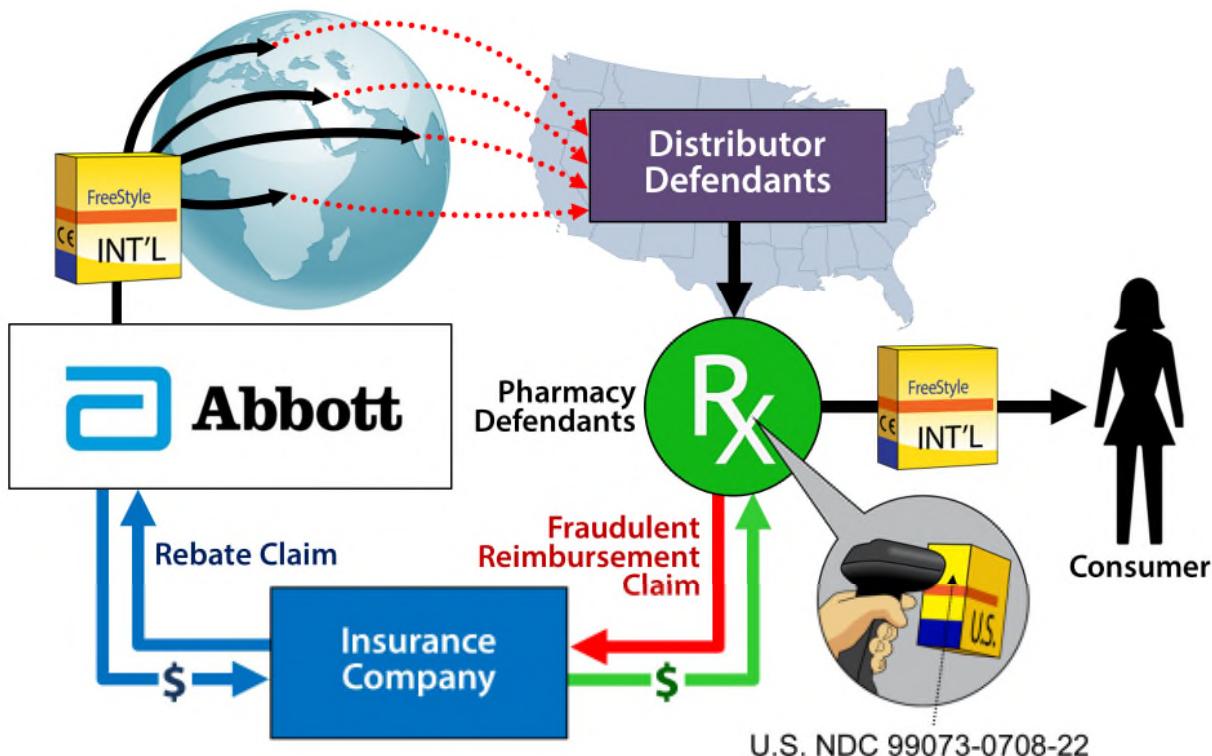
127. Defendants' fraud is first visited on U.S. consumers. By dispensing diverted international FreeStyle test strips, Defendants are exposing each consumer to the threat of confusion and misuse posed by the material differences between U.S. and international FreeStyle test strips. U.S. consumers, however, see no savings and in fact pay the same amount for a box of diverted international test strips as they would for a box of U.S. FreeStyle test strips. So for the same price, these consumers are receiving a box of FreeStyle test strips that are not approved for sale in the United States.

128. For each of these sales Defendants have made and continue to make, they are then submitting a false claim for reimbursement with the consumer's insurer. Based on the falsely adjudicated NDC number, insurance companies have paid out and continue to pay out reimbursements to Defendants.

129. These fraudulent adjudications are then forwarded on to Abbott. Just as insurance companies do not provide reimbursements for products without an NDC number, Abbott does not provide rebates to insurers unless the pharmacies provide the NDC number of a

rebate-eligible product they claim to have dispensed. For every reimbursement wrongfully paid by an insurer based on a fraudulent NDC number, the insurer then submits a claim for a rebate from Abbott pursuant to their agreed-upon rebate structure. And as Defendants know, as it is fundamental to their scheme, it is then Abbott that pays the rebate to the insurer based on the same fraudulent NDC number caused to be transmitted by Defendants.

130. Defendants' conspiracy to divert international FreeStyle test strips and fraudulently adjudicate sales of diverted test strips is illustrated in **Figure 12**:



Illegal Distribution Chain

Figure 12

131. Abbott has suffered and continues to suffer significant losses at the hand of Defendants' fraudulent scheme. For each sale of diverted international FreeStyle test strips for which Abbott pays a rebate, Abbott first receives the foreign list price, which is significantly lower than the U.S. list price. Then, Abbott pays a rebate that it is not supposed to pay. Thus,

each of these transactions results in a net loss for Abbott.

132. Abbott's financial loss is Defendants' gain. Because over 95% of U.S. consumers purchase FreeStyle test strips with a prescription and insurance, there is minimal return—and thus minimal incentive—for Defendants to sell diverted international FreeStyle test strips over-the-counter for cash.

133. Diverted international FreeStyle test strips are very profitable for Defendants, though, precisely because they fraudulently submit their sales directly for reimbursements and indirectly for rebates. This is the central purpose of Defendants' conspiracy. And each Defendant plays a critical role in this conspiracy.

Defendants' Involvement in the Fraudulent Scheme

134. Each Defendant participated in and/or aided and abetted the scheme just described and conspired with each other Defendant to further the scheme. To investigate and expose this conspiracy, Abbott arranged for and made purchases of diverted international FreeStyle test strips from each defendant.

135. **Adelphia.** On June 8, 2015, Abbott purchased 12 boxes of diverted 50-count FreeStyle Lite test strips from Adelphia. These boxes were marked with an expiration date of January 2017 and Lot Number 1485206, which was intended for sale in the United Kingdom and Jamaica. These boxes of test strips did not have an NDC number or a U.S. toll-free phone number. In comparison with FreeStyle Lite test strips packaged for sale in the U.S., the outer packaging of these boxes was missing several warnings and instructions, including "For *in vitro* diagnostic testing"; "Do not reuse"; and "Store at room temperature between 40° F - 86° F (4° C - 30° C)". In addition, there were several foreign symbols present on the outer packaging of each box, including a "CE" mark, which indicates the box was packaged for sale in the European Economic Area. This diverted international product also contained an instructional insert that is

materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the inserts in these boxes of diverted FreeStyle test strips included Greek and Portuguese language and instruct patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

136. **Save Rite Medical.** On September 10, 2015, Abbott purchased 1 case (12 boxes) of diverted 50-count FreeStyle Lite test strips from Save Rite. Save Rite delivered these test strips via UPS Ground from Brooklyn, New York to Lake Success, New York in the Eastern District of New York. These boxes were shipped in an Abbott case marked with Lot Number 1502212 and an expiration date of February 2017. The boxes within the case, however, had a different Lot Number, 1506907, and different expiration date, October 2016. Lot Number 1506907 was intended for sale in India. These boxes of test strips did not have an NDC number or U.S. toll-free number, and state “For sale in India only.” The outer packaging of these boxes was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the inserts in these boxes of diverted FreeStyle test strips instruct patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

137. **Matrix Distributors.** On September 24, 2015, Abbott purchased 1 case (12 boxes) of diverted 50-count FreeStyle Lite test strips from Matrix. Matrix delivered these test strips via UPS Ground from Edison, New Jersey to Lake Success, New York in the Eastern District of New York. This case was shipped in an unmarked box that housed an Abbott branded case. The case was marked with Lot Number 1511114 and an expiration date of May 2017. While the case contained 12 boxes of FreeStyle Lite test strips with the same Lot Number and expiration date, the case bore obvious signs of having been opened and resealed. Lot Number 1511114 was intended for sale in Greece and Spain. These boxes of test strips did not have an NDC number or U.S. toll-free number. The outer packaging of these boxes included Greek and Portuguese language and was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the inserts in these boxes of diverted FreeStyle test strips included Greek and Portuguese language and instruct patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

138. **H&H.** On September 11, 2015, Abbott purchased 12 boxes of diverted 50-count FreeStyle Lite test strips from H&H. When placing this order, the salesperson for H&H, Michael Leonhard, stated that the international test strips were the same as the test strips manufactured for sale in the U.S., but with different packaging. H&H delivered these test strips via FedEx Ground from Troy, Michigan to Lake Success, New York in the Eastern District of

New York. These test strips were shipped in an unmarked box containing 12 loose boxes. The boxes were marked with the same expiration date of May 2017, but with various Lot Numbers: 6 boxes were marked with Lot Number 1511219, which were intended for sale in the United Kingdom and Ireland; 2 boxes were marked with Lot Number 1511813, which were intended for sale in the United Kingdom and Ireland; 2 boxes were marked with Lot Number 1510701, which were intended for sale in the United Kingdom; 1 box was marked with Lot Number 1512004, which was intended for sale in the United Kingdom and Jamaica; and 1 box was marked with Lot Number 1510616, which was intended for sale in the United Kingdom. These boxes of test strips did not have an NDC number or U.S. toll-free number. The outer packaging of these boxes was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the inserts in these boxes of diverted FreeStyle test strips included Greek and Portuguese language and instruct patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States. Abbott also purchased boxes with Lot Numbers 1511219 and 1511813 from defendant SimpleMed Supply; a box with Lot Number 1510701 from defendant Bay Pharmacy; and a box with Lot Number 1512004 from defendant B & T Marlboro Pharmacy and defendant La Ruche Pharmacy.

139. **VIP International.** On September 22, 2015, Abbott purchased 12 boxes of 50-count FreeStyle Lite test strips from VIP. VIP delivered these test strips via UPS Ground

from Staten Island, New York to Lake Success, New York in the Eastern District of New York. These test strips were shipped in an unmarked box which housed a second unmarked box containing 12 loose boxes. Ten of these boxes were diverted international FreeStyle Lite test strips, which were marked with various expiration dates and Lot Numbers: 6 boxes were marked with Lot Number 1513101 and an expiration date of May 2017, which were intended for sale in India; 3 boxes were marked with Lot Number 1513803 and an expiration date of June 2017, which were intended for sale in Spain and Greece; and 1 box was marked with Lot Number 1504916 and an expiration date of March 2017, which was intended for sale in the United Kingdom and Ireland. These boxes of test strips did not have an NDC number or U.S. toll-free number. The outer packaging of these boxes was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the inserts in these boxes of diverted FreeStyle test strips instruct patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

140. **SimpleMed Supply.** On September 18, 2015, Abbott purchased 12 boxes of diverted 50-count FreeStyle Lite test strips from SimpleMed. SimpleMed delivered these test strips via UPS Ground from Salt Lake City, Utah to Lake Success, New York in the Eastern District of New York. These test strips were shipped in an unmarked box containing 12 loose boxes. The boxes were marked with various expiration dates and Lot Numbers: 4 boxes were

marked with Lot Number 1511219 and an expiration date of May 2017, which were intended for sale in the United Kingdom and Ireland; 3 boxes were marked with Lot Number 1511802 and an expiration date of June 2017, which were intended for sale in the United Kingdom and Ireland; 3 boxes were marked with Lot Number 1514510 and an expiration date of June 2017, which were intended for sale in the United Kingdom; 1 box was marked with Lot Number 1511813 and an expiration date of May 2017, which was intended for sale in the United Kingdom and Ireland; and 1 box was marked with Lot Number 1515506 and an expiration date of June 2017, which was intended for sale in the United Kingdom. These boxes of test strips did not have an NDC number or U.S. toll-free number. The outer packaging of these boxes was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the inserts in these boxes of diverted FreeStyle test strips included Greek and Portuguese language and instruct patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States. Abbott also purchased boxes with Lot Numbers 1511219 and 1511813 from defendant H&H; a box with Lot Number 1511802 from defendant The Modern Chemist; and a box with Lot Number 1514510 from defendant Sunrise Family Pharmacy.

141. **Budget Drugs Pharmacy.** On September 29, 2015, Abbott purchased 1 case (12 boxes) of diverted 50-count FreeStyle Lite test strips from Budget Drugs. Budget Drugs delivered these test strips via USPS Priority Mail from Hallandale, Florida to Lake Success, New

York in the Eastern District of New York. This case was shipped in a “ProPak” box that housed an Abbott branded case. The case was marked with Lot Number 1514819 and an expiration date of June 2017. The case bore obvious signs of having been opened and resealed, and the boxes within the case had a different Lot Number, 1506512, and different expiration date, March 2017. Moreover, each of these boxes was repackaged in an unauthorized replica of a box intended for sale in the European Union; and an unauthorized label was adhered to the vial of test strips located inside each box. This repackaging was not performed under Abbott’s oversight and was therefore not subjected to Abbott’s quality-control standards and procedures. Lot Number 1506512 was intended for sale in France. These boxes of test strips did not have an NDC number or U.S. toll-free number. In addition to the fact that the labeling on the package and vial was unauthorized, the outer packaging of these boxes was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the inserts in these boxes of diverted FreeStyle test strips instruct patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

142. **Diabetes Supplies 4 Less.** On October 2, 2015, Abbott purchased 5 boxes of diverted 100-count FreeStyle Lite test strips from Diabetes Supplies 4 Less. Diabetes Supplies 4 Less delivered these test strips via UPS Next Day Air from Boynton Beach, Florida to Lake Success, New York in the Eastern District of New York. These test strips were shipped in

an unmarked box containing 5 loose boxes. The boxes were marked with various expiration dates and Lot Numbers: 2 boxes were marked with Lot Number 1476020 and an expiration date of April 2016; 1 box was marked with Lot Number 1475202 and an expiration date of September 2016; 1 box was marked with Lot Number 1478604 and an expiration date of May 2016; and 1 box was marked with Lot Number 11475506 and an expiration date of April 2016. Four of the boxes were manufactured for sale in Australia, while Lot Number 1475202 was manufactured for sale in the United Kingdom. These boxes of test strips did not have an NDC number or U.S. toll-free number. The outer packaging of these boxes was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the inserts in these boxes of diverted FreeStyle test strips instruct patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

143. **Berkeley Drugs.** On September 16, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from Berkeley Drugs. This box was marked with an expiration date of April 2017 and Lot Number 1508503, which was intended for sale in the United Kingdom. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present

on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States. Abbott also purchased a box with Lot Number 1508503 from defendant Kira’s Pharmacy.

144. **Careway Pharmacy Inc.** On September 16, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from Careway Pharmacy. This box was marked with an expiration date of May 2017 and Lot Number 1511106, which was intended for sale in the United Kingdom. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

145. On October 1, 2015, Abbott arranged for a second purchase to be made from Careway Pharmacy. This time, however, the purchasing individual had diabetes and a

prescription for test strips. This person purchased one box of 50-count Abbott FreeStyle Lite test strips from Careway Pharmacy. This box of test strips was marked with an expiration date of May 2017 and Lot Number 1510701. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

146. Despite the lack of an NDC number on the outer box, the receipt from this purchase listed “NDC# 53885-0244-50,” which is not the NDC number for 50-count boxes of U.S. FreeStyle Lite test strips, but is instead the NDC number for OneTouch Ultra test strips, which are manufactured and sold by LifeScan. While Careway Pharmacy dispensed a box of diverted international FreeStyle test strips, it adjudicated a sale of OneTouch Ultra test strips under the purchaser’s prescription benefit. Furthermore, while the receipt suggests the purchaser paid a \$15.00 copayment for this box, the pharmacy representative instructed him that he did not have to pay a copayment and therefore he did not. The purchase was covered by and processed through the purchaser’s insurance with Express. Thus, the Defendants are not only causing fraudulent rebate claims to be submitted to Abbott, but may also be causing fraudulent rebate claims to be submitted to other test strip manufacturers including LifeScan.

147. **Harrico Galler Drug.** On September 16, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from Harrico Galler. This box was marked with an expiration date of October 2016 and Lot Number 1476607, which was intended for sale in the United Kingdom. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

148. On September 21, 2015, Abbott arranged for a second purchase to be made from Harrico Galler Drug. This time, however, the purchasing individual had diabetes and a prescription for test strips. This person purchased one box of 50-count Abbott FreeStyle Lite test strips from Harrico Galler Drug Corp. She paid a \$20.00 copayment for this box. The remainder of the purchase for these test strips was covered by and processed through her insurance with Blue Cross/Blue Shield of New York. Like the previous purchase from Harrico Galler Drug, this box of test strips was marked with an expiration date of October 2016 and Lot Number 1476607. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature

between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States. Despite the lack of an NDC number on the outer box, the receipt from this purchase listed “NDC# 99073-708-22,” which is the NDC number for 50-count boxes of FreeStyle Lite test strips sold by Abbott in the United States. That NDC number was not listed anywhere on the packaging or the insert of the box of test strips.

149. **The Modern Chemist.** On September 16, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from Modern Chemist. This box was marked with an expiration date of June 2017 and Lot Number 1511802, which was intended for sale in the United Kingdom and Ireland. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions

contained in boxes manufactured for sale in the United States. Abbott also received boxes with Lot Number 1511802 from defendant SimpleMed.

150. **Vanderveer Pharmacy.** On September 16, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from Vanderveer Pharmacy. This box was marked with an expiration date of February 2017 and Lot Number 1502818, which was intended for sale in the United Kingdom. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

151. **Kira’s Pharmacy.** On September 21, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from Kira’s Pharmacy. This box was marked with an expiration date of April 2017 and Lot Number 1508503, which was intended for sale in the United Kingdom. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international

product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States. Abbott also purchased a box with Lot Number 1508503 from defendant Berkeley Drugs.

152. **Eliyahus Pharmacy.** On September 21, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from Eliyahus Pharmacy. This box was marked with an expiration date of November 2016 and Lot Number 1479508, which was intended for sale in France. This box was repackaged in an unauthorized replica of a box intended for sale in the European Union; and an unauthorized label was adhered to the vial of test strips located inside the box. This repackaging was not performed under Abbott's oversight and was therefore not subjected to Abbott's quality-control standards and procedures. This box of test strips did not have an NDC number or a U.S. toll-free phone number. In addition to the fact that the labeling on the package and vial was unauthorized, the outer packaging of this box was missing several warnings and instructions, including "For *in vitro* diagnostic testing"; "Do not reuse"; and "Store at room temperature between 40° F - 86° F (4° C - 30° C)". In addition, there were several foreign symbols present on the outer packaging of each box, including the "CE" mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in

instructions contained in boxes manufactured for sale in the United States. Abbott also purchased a box with Lot Number 1479508 from defendant 110 Pharmacy & Surgical.

153. **Global Care Pharmacy.** On September 21, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from Global Care. This box was marked with an expiration date of May 2017 and Lot Number 1510515, which was intended for sale in the United Kingdom and Ireland. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

154. **8th Avenue Pharmacy.** On September 21, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from 8th Avenue Pharmacy. This box was marked with an expiration date of February 2017 and Lot Number 1503603, which was intended for sale in Israel and Lithuania. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box included Arabic language and was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE”

mark, as well as Arabic language. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips included Arabic and French language and instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

155. **Sunrise Family Pharmacy.** On September 21, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from Sunrise Family. This box was marked with an expiration date of June 2017 and Lot Number 1514510, which was intended for sale in the United Kingdom. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips included Greek and Portuguese language and instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States. Abbott also received boxes with Lot Number 1514510 from defendant SimpleMed.

156. **Bay Pharmacy.** On September 28, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from Bay Pharmacy. This box was marked with an

expiration date of May 2017 and Lot Number 1510701, which was intended for sale in the United Kingdom. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips included Greek and Portuguese language and instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States. Abbott also received boxes with Lot Number 1510701 from defendant H&H.

157. **B & T Marlboro Pharmacy.** On September 28, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from B & T Marlboro Pharmacy. This box was marked with an expiration date of May 2017 and Lot Number 1512004, which was intended for sale in the United Kingdom and Jamaica. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international product also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips included Greek

and Portuguese language and instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States. Abbott also received a box with Lot Number 1512004 from defendant H&H and defendant La Ruche Pharmacy.

158. **110 Pharmacy & Surgical.** On October 7, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from 110 Pharmacy & Surgical. This box was marked with an expiration date of November 2016 and Lot Number 1479508, which was intended for sale in France. This box was repackaged in an unauthorized replica of a box intended for sale in the European Union; and an unauthorized replica of the label was adhered to the vial of test strips located inside the box. This repackaging was not performed under Abbott's oversight and was therefore not subjected to Abbott's quality-control standards and procedures. This box of test strips did not have an NDC number or a U.S. toll-free phone number. In addition to the fact that the labeling on the package and vial was unauthorized, the outer packaging of this box was missing several warnings and instructions, including "For *in vitro* diagnostic testing"; "Do not reuse"; and "Store at room temperature between 40° F - 86° F (4° C - 30° C)". In addition, there were several foreign symbols present on the outer packaging of each box, including the "CE" mark. This diverted international box also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States. Abbott also purchased a box with Lot Number 1479508 from defendant Eliyahus

Pharmacy.

159. **La Ruche Pharmacy.** On October 7, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from La Ruche Pharmacy. This box was marked with an expiration date of May 2017 and Lot Number 1512004, which was intended for sale in the United Kingdom and Jamaica. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign symbols present on the outer packaging of each box, including the “CE” mark. This diverted international box also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips included Greek and Portuguese language and instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States. Abbott also received a box with Lot Number 1512004 from defendant H&H and defendant B & T Marlboro Pharmacy.

160. **Estates Pharmacy.** On October 7, 2015, Abbott purchased one box of diverted 50-count FreeStyle Lite test strips from Estates Pharmacy. This box was marked with an expiration date of May 2017 and Lot Number 1510604, which was intended for sale in the United Kingdom, Ireland, and Jamaica. This box of test strips did not have an NDC number or a U.S. toll-free phone number. The outer packaging of this box was missing several warnings and instructions, including “For *in vitro* diagnostic testing”; “Do not reuse”; and “Store at room temperature between 40° F - 86° F (4° C - 30° C)”. In addition, there were several foreign

symbols present on the outer packaging of each box, including the “CE” mark. This diverted international box also contained an instructional insert that is materially different in many ways from the insert contained in all boxes of FreeStyle test strips packaged for sale in the United States. For example, the insert in this box of diverted FreeStyle test strips instructs patients to test from sites including the hand, forearm, calf, and thigh, all of which are test site locations that have been rejected by the U.S. FDA and are, therefore, not included in instructions contained in boxes manufactured for sale in the United States.

161. All of these sales demonstrate each Defendant’s necessary connection and participation in the conspiracy. This cannot be done alone. The importers, the distributors, and the pharmacies are all necessary to the success of the conspiracy. They must work together to make their conspiracy successful—i.e., profitable.

Defendants’ Prior Fraudulent and Criminal Acts

162. For several Defendants, this is not the first time they have been involved in the unauthorized sale of blood glucose test strips. Defendants Matrix; Adelphia; and H&H have each been sued previously for the unlawful import and sale of LifeScan OneTouch blood glucose test strips—a competitor product to Abbott’s FreeStyle test strips.

163. **Matrix.** In October 2006, Matrix was sued by Johnson & Johnson and its subsidiary, LifeScan, Inc., for the unlawful manufacture, sale, and distribution of counterfeit LifeScan OneTouch Ultra brand of blood glucose test strips. *See Complaint, Johnson & Johnson v. Champion Sales, Inc. et al., No. 1:06-cv-05451, Dkt. No. 1 (E.D.N.Y.).*

164. Lifescan’s suit alleged claims for trademark infringement in violation of the Lanham Act, false descriptions, and false designations of origin in commerce in violation of Section 43 of the Lanham Act and Section 349 of the New York General Business Law, trademark dilution in violation of Section 43 of the Lanham Act and New York General Business

Law Section 360-l, and common law unjust enrichment and unfair competition.

165. In September 2015, Judge Townes signed an order permanently enjoining Matrix from “buying, selling, distributing or using in commerce in any way” blood glucose test strips that constituted “Diverted Product”—that is, in part, “blood glucose test strips … that are contained in packaging that states ‘Not for Sale in the U.S.’; or are contained in packaging that does not have [an NDC number] listed; or are contained in packaging that bears the ‘CE’ mark; or are contained in packaging on which the primary language is not English; or are covered with one or more stickers that are not price tags and were not applied by Plaintiffs.” Consent Judgment and Permanent Injunction, *Johnson & Johnson v. Champion Sales, Inc. et al.*, No. 1:06-cv-05451, Dkt. No. 292 at 1 (E.D.N.Y. Sept. 28, 2015).

166. The conduct Matrix has been enjoined from is the very course of conduct that Matrix has engaged in in this case, only now with Abbott’s FreeStyle blood glucose test strips.

167. **Adelphia.** Adelphia is a recidivist infringer, having been sued on multiple occasions for the unlawful sale and distribution of diverted and counterfeit of blood glucose test strips.

168. In 2014, LifeScan also brought suit against Adelphia and its owner, defendant Yudah (“Lenny”) Neuman, alleging that Adelphia had intentionally imported foreign, gray-market versions LifeScan test strips into the United States. *See* Complaint, *Johnson & Johnson et al. v. Adelphia Discount Services, Inc. et al.*, No. 1:14-cv-02311, Dkt. No. 1 (E.D.N.Y. April 10, 2014). The complaint alleged gray-market diversion going as far back as 2011, when the FDA had first seized a shipment of counterfeit test strips intended for Adelphia, and further alleged that Adelphia had also breached a 2013 settlement agreement in which it agreed to refrain from distributing, marketing, or selling LifeScan test strips intended for

overseas markets in the United States. *Id.* LifeScan alleged that, notwithstanding the 2013 agreement, Adelphia had continued to engage in gray-market sales of the test strips.

169. The dispute was resolved with Judge Dearie permanently enjoining Adelphia from selling LifeScan OneTouch Ultra test strips that were not meant for sale in the United States. Consent Judgment, Johnson & Johnson et al. v. Adelphia Discount Services, Inc. et al, No. 1:14-cv-02311, Dkt. No. 38 at 2 (E.D.N.Y. Aug. 7, 2015).

170. Yudah Neuman, was only recently released from prison following a conviction on fraud charges. Neuman pled guilty to attempt and conspiracy to commit mail fraud in connection with a stranger-originated life insurance scam. He was sentenced to a year and a day in prison and ordered to forfeit \$300,000. Judgment in a Criminal Case, USA v. Yudah Neuman, Case no. 1:11-cr-00134-SJ, filed in the U.S. District Court for the Eastern District of New York on March 11, 2014.

171. **H&H.** Like Adelphia, H&H is a recidivist when it comes to the unlawful sale and distribution of diverted and/or counterfeit test strips.

172. H&H has been the subject of a series of government seizures, warning letters, and enforcement actions dating as far back as 2005 concerning its purchase and sale of non-FDA approved blood glucose test strips and related medical devices. As recently as 2012, the FDA warned H&H that its practices for purchasing, storing and selling glucose test strips were in violation of federal regulations. *See* Warning Letter 2012-DET-09, U.S. Food & Drug Administration (March 27, 2012), *available* at www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm297885.htm.

173. H&H has also been the subject of two civil suits relating to its bad conduct.

174. In 2009, H&H and its principal agent, defendant Howard Goldman, were

among several defendants sued by Johnson & Johnson and LifeScan in connection with the manufacture and distribution of counterfeit OneTouch test strips. *See Sixth Amended Complaint, Johnson & Johnson et al. v. South Pointe Wholesale, Inc., et al.*, No. 08-civ-1297, Dkt. No. 265 (E.D.N.Y. May 21, 2009). In that case, H&H acknowledged that it purchased more than 20,000 boxes of LifeScan test strips from abroad, and Chief Magistrate Judge Gold concluded that all of those boxes were counterfeit. Report & Recommendation, *South Pointe Wholesale, Inc.*, No. No. 08-civ-1297, Dkt. No. 769 at 18, 40-41 (E.D.N.Y. Mar. 28, 2014).

175. LifeScan sued H&H again in 2014, this time in Massachusetts federal court, making allegations similar to those that Abbott makes here: that H&H's sale of diverted international test strips within the United States was illegal. Complaint, *Johnson & Johnson v. H&H Wholesale Services, Inc.*, No. 1:14-cv-10346, Dkt. No. 1 (D. Mass. Feb. 18, 2014). LifeScan and H&H settled the New York counterfeiting case and the Massachusetts illegal diversion case, with H&H paying LifeScan \$2 million. Consent Judgment and Permanent Injunction at 1, *LifeScan v. South Pointe Wholesale, Inc., et al.*, No. 08-civ-1297, Dkt. No. 816 (E.D.N.Y. Nov. 25, 2014). The judgment signed by Judge Townes permanently enjoined H&H from selling diverted international LifeScan test strips. *Id.* After this settlement, LifeScan agreed to dismiss its Massachusetts lawsuit against H&H. Stipulation of Dismissal, *Johnson & Johnson v. H&H Wholesale Services, Inc.*, No. 1:14-cv-10346, Dkt. No. 40 (D. Mass. Dec. 4, 2014).

176. While Defendants' past conduct is certainly revelatory, their conduct continues to date. Defendants' conspiracy continues to mislead and confuse consumers; continues to defraud third-party payors; and continues to cause irreparable and monetary harm to Abbott. Every time Defendants file a false claim for reimbursement, they commit another fraud.

FIRST CLAIM FOR RELIEF

**Federal Trademark Infringement
15 U.S.C. §1114(1) (Lanham Act Section 32)
(Against all Defendants)**

177. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

178. Abbott is the owner of all right, title and, interest in and to the FreeStyle Marks (as set forth above).

179. Defendants, without authorization, have imported into the United States, and/or distributed and/or sold in the United States, and/or received in interstate commerce, diverted international FreeStyle test strips featuring the FreeStyle Marks, which products are materially different from the U.S. FreeStyle test strips authorized by Abbott for sale in the United States. Such actions are likely to cause confusion, mistake, or deception as to the source of origin, sponsorship or approval of the diverted international FreeStyle test strips in that purchasers and others in this judicial district and elsewhere in the United States are likely to believe Abbott authorizes and controls the sale of Defendants' diverted international FreeStyle test strips, or that Defendants are associated with or related to Abbott or are authorized by Abbott to sell FreeStyle products in the United States.

180. Defendants' acts have injured or are likely to injure Abbott's image and reputation with consumers in this judicial district and elsewhere in the United States by creating confusion about, and/or dissatisfaction with, Abbott's FreeStyle products.

181. Defendants' acts have injured or are likely to injure Abbott's reputation in this judicial district and elsewhere in the United States by causing customer dissatisfaction, a diminution of the value of the goodwill associated with the FreeStyle Marks, and a loss of sales and/or market share to Abbott's competition.

182. Defendants' acts have been committed deliberately and willfully, with

knowledge of Abbott's exclusive rights and goodwill in the FreeStyle Marks, and with knowledge of the infringing nature of the marks when used in connection with the diverted international FreeStyle test strips. Defendants' acts have also been committed with bad faith and the intent to cause confusion, or to cause mistake and/or to deceive.

183. As a result of Defendant's trademark infringement, Abbott has suffered and will continue to suffer substantial and irreparable injury, loss and damage to its rights in and to the FreeStyle Marks, and damage to the goodwill associated therewith, for which it has no adequate remedy at law.

184. If not restrained, Defendant will have unfairly derived and will continue to derive income, profits, and business opportunities as a result of their acts of infringement.

185. As the acts alleged herein constitute infringement of the FreeStyle Marks under 15 U.S.C. § 1114(1), and as Abbott has no adequate remedy at law, Abbott is entitled to injunctive relief as well as to Defendant's profits, Abbott's damages, and other remedies provided by 15 U.S.C. §§ 1116, 1117 and 1118, and to reasonable attorneys' fees and prejudgment interest pursuant to 15 U.S.C. § 1117.

SECOND CLAIM FOR RELIEF

**Federal Unfair Competition
15 U.S.C. § 1125(a)(i)(A) (Lanham Act Section 43(a))
(Against all Defendants)**

186. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

187. Defendants have, without authorization, imported into the United States and/or distributed and/or sold in the United States and/or received in interstate commerce, diverted international FreeStyle test strips featuring the FreeStyle Marks, which products are materially different from the U.S. FreeStyle test strips authorized by Abbott for sale in the

United States. Such use is likely to cause confusion, or to cause mistake and/or to deceive as to the affiliation, connection or association of Defendants with Abbott, and as to the origin, sponsorship or approval by Abbott of Defendants' diverted international FreeStyle test strips and the commercial activities related to Defendants' diverted international FreeStyle test strips.

188. Defendants' acts constitute a false representation and a false designation of origin in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

189. Defendants' acts have been committed with knowledge of Abbott's exclusive common law rights and goodwill in the FreeStyle Marks, as well as with bad faith and the intent to cause confusion or mistake, and/or to deceive.

190. Abbott has suffered and, if Defendants are not enjoined, will continue to suffer great and irreparable injury, loss, and damage to its rights in and to the FreeStyle Marks and to the goodwill associated therewith for which Abbott has no adequate remedy at law.

191. If not restrained, Defendants will have unfairly derived and will continue to derive income, profits, and business opportunities as a result of their acts of infringement.

192. As the acts alleged herein violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and as Abbott has no adequate remedy at law, Abbott is entitled to injunctive relief and to Defendants' profits, Abbott's damages, and other remedies provided by 15 U.S.C. §§ 1116, 1117 and 1118, and to reasonable attorneys' fees and prejudgment interest pursuant to 15 U.S.C. § 1117.

THIRD CLAIM FOR RELIEF
Common Law Unfair Competition
(Against all Defendants)

193. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

194. Defendants' acts constitute an infringement of Abbott's trademark rights

in violation of common law, including the common law of the State of New York and elsewhere.

195. As a result of Defendants' acts Abbott has suffered and, if Defendants are not enjoined, will continue to suffer great and irreparable injury, loss, and damage to its rights in and to the FreeStyle Marks, and to the goodwill associated therewith for which Abbott has no adequate remedy at law.

FOURTH CLAIM FOR RELIEF

**Federal Trademark Dilution
15 U.S.C. § 1125(c) (Lanham Act Section 43(c))
(Against all Defendants)**

196. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

197. Abbott's FreeStyle Marks are famous and distinctive within the meaning of 15 U.S.C. § 1125(c).

198. Abbott's FreeStyle Marks are widely recognized by the general consuming public of the United States as a designation of source of Abbott's goods, including FreeStyle products.

199. Since the FreeStyle marks have become famous, Defendants have utilized marks that are likely to cause dilution by blurring and/or tarnishment of Abbott's famous FreeStyle marks.

200. Defendants' acts greatly and irreparably damage Abbott and will continue to do so unless restrained by this Court. Therefore, Abbott is without an adequate remedy at law and is entitled to, among other things, an order enjoining and restraining Defendants from selling diverted international FreeStyle test strips.

FIFTH CLAIM FOR RELIEF

**State Law Trademark Dilution
(Against all Defendants)**

201. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

202. Abbott's FreeStyle Marks are distinctive under state law, including New York General Business Law § 360-1.

203. Defendants' acts are likely to cause dilution by blurring and/or tarnishment, and damage the business reputation of Abbott in violation of state law, including New York General Business Law § 360-1.

204. Through their acts, Defendants have injured and are continuing to injure Abbott's business reputation and/or have diluted and are continuing to dilute the distinctive quality of the FreeStyle Marks, in violation of state law, including New York General Business Law § 360-1.

205. Defendants' acts greatly and irreparably damage Abbott and will continue to do so unless restrained by this Court. Therefore, Abbott is without an adequate remedy at law and is entitled to, among other things, an order enjoining and restraining Defendants from selling diverted international FreeStyle test strips.

SIXTH CLAIM FOR RELIEF

**State Law Deceptive Business Practices
(Against all Defendants)**

206. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

207. Defendants' acts were consumer-oriented.

208. Defendants' acts were materially misleading.

209. Defendants' acts have caused and are continuing to cause injury to Abbott

in violation of state law, including New York General Business Law § 349.

210. Defendants' acts greatly and irreparably damage Abbott and will continue to do so unless restrained by this Court. Therefore, Abbott is without an adequate remedy at law and is entitled to, among other things, an order enjoining and restraining Defendants from selling diverted international FreeStyle test strips.

SEVENTH CLAIM FOR RELIEF

**Unjust Enrichment
(Against all Defendants)**

211. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

212. The Defendants made false representations and material omissions in fraudulently seeking reimbursement for diverted international boxes of FreeStyle test strips.

213. As a result of these false representations and material omissions, Defendants wrongfully obtained a monetary benefit to which they were not legally entitled.

214. Each individual Defendant personally benefitted as a result of the additional profits the Defendants reaped as a result of the diversion scheme.

215. Defendants have no right to retain these unjust gains.

216. If Defendants are permitted to keep this monetary benefit, it would be manifestly unjust.

217. By selling diverted international FreeStyle test strips in the United States, Defendants have been unjustly enriched at Abbott's expense in violation of the common law of New York and elsewhere.

EIGHTH CLAIM FOR RELIEF

**Violation of Federal RICO, 18 U.S.C. § 1962(c)
(Against all Defendants)**

218. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

219. At all relevant times, Abbott Laboratories, Abbott Diabetes Care Inc., and Abbott Diabetes Care Sales Corporation were “persons” within the meaning of RICO, 18 U.S.C. §§ 1961(3) & 1964(c).

220. At all relevant times, each Defendant was a “person” within the meaning of RICO, 18 U.S.C. §§ 1961(3) & 1962(c).

221. Defendants formed an association-in-fact for the purpose of defrauding Abbott and insurers, including private insurers and Medicare and Medicaid. This association-in-fact was an “enterprise” within the meaning of RICO, 18 U.S.C. § 1961(4). This enterprise consists of Defendants as well as other importers, distributors, and pharmacies who have yet to be discovered. Defendants organized their RICO enterprise into a continuing and cohesive unit with specific and assigned responsibilities. All Defendants participated in the operation and management of the enterprise. At all relevant times, this enterprise was engaged in, and its activities affected, interstate and foreign commerce, within the meaning of RICO, 18 U.S.C. § 1962(c)

222. Each Defendant, by engaging in the acts set forth above, conducted or participated, directly or indirectly, in the conduct of the enterprise’s affairs through a “pattern of racketeering activity” within the meaning of RICO, 18 U.S.C. § 1961(1) & (5), in violation of RICO, 18 U.S.C. § 1962(c).

223. Defendants, on multiple occasions, and in furtherance of their scheme to defraud and to obtain money by means of false and fraudulent pretenses, knowingly caused to be sent and delivered across state lines by commercial interstate carrier shipments of diverted international FreeStyle test strips. These acts constituted violations of the federal mail fraud

statute, 18 U.S.C. § 1341.

224. Defendants, on multiple occasions and in furtherance of their scheme to defraud and to obtain money by means of false and fraudulent pretenses, knowingly caused to be transmitted, by means of wire communication in interstate or foreign commerce, writings, signs, signals, pictures, and sounds, in violation of the federal wire fraud statute, 18 U.S.C. § 1343. Each false insurance reimbursement claim Defendants made was transmitted by means of wire communication in interstate or foreign commerce and constituted a separate violation of 18 U.S.C. § 1343, and a separate act of racketeering.

225. Defendants also knowingly caused to be transmitted, by means of wire communication in interstate or foreign commerce, false statements to Abbott. Defendants also knowingly caused to be transmitted, by means of wire communication in interstate or foreign commerce, false statements to the insurance companies covering the product manufactured by these other manufacturers, namely, statements that the product Defendants were dispensing was product packaged and intended for retail sale in the United States (when in fact it was product packaged and intended for sale outside the United States). All of these acts constituted separate violations of 18 U.S.C. § 1343.

226. Each Defendant committed and/or aided and abetted the commission of two or more of these racketeering acts in violation of 18 U.S.C. §§ 1341 and 1343. In fact, Defendants' racketeering acts were and are multiple, repeated, and continuous.

227. These multiple racketeering acts were related and constituted a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5). The acts alleged were related to each other by virtue of common participants; common victims (Abbott and the insurance companies covering those products); a common method of commission; and the common purpose and common result of defrauding Abbott, Medicare and Medicaid, and other insurers,

and of enriching Defendants while concealing their fraudulent activities. The pattern of racketeering activity continues to date.

228. Abbott was directly and proximately injured by Defendants' pattern of racketeering activity. As a result of their misconduct, Defendants are liable to Abbott for these injuries.

229. Pursuant to 18 U.S.C. § 1964(c), Plaintiffs are entitled to recover threefold their damages plus costs and attorneys' fees.

NINTH CLAIM FOR RELIEF

**Conspiracy to Violate Federal RICO, 18 U.S.C. § 1962(d)
(Against all Defendants)**

230. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

231. At all relevant times, Abbott Laboratories, Abbott Diabetes Care Inc., and Abbott Diabetes Care Sales Corporation were "persons" within the meaning of RICO, 18 U.S.C. §§ 1961(3) & 1964(c).

232. At all relevant times, each Defendant was a "person" within the meaning of RICO, 18 U.S.C. §§ 1961(3) & 1962(d).

233. Each Defendant was associated with the enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise through the pattern of racketeering activity described herein, in violation of 18 U.S.C. § 1962(d).

234. Defendants committed and caused to be committed a series of overt acts in furtherance of the conspiracy and to affect the objects thereof, including but not limited to the acts set forth above.

235. Abbott was directly and proximately injured by Defendants' pattern of

racketeering activity. As a result of their misconduct, Defendants are liable to Abbott for these injuries.

236. Pursuant to 18 U.S.C. § 1964(c), Plaintiffs are entitled to recover threefold their damages plus costs and attorneys' fees.

TENTH CLAIM FOR RELIEF

**Importation of Goods Bearing Infringing Marks
15 U.S.C. § 1124
(Against all Defendants)**

237. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

238. By illegally importing diverted international FreeStyle test strips from foreign countries with the intent of inducing diabetic consumers into believing that the products are authorized for resale in the United States, Defendants have violated 15 U.S.C. § 1124.

239. Abbott has been, and continues to be, damaged by Defendants' activities and conduct. Defendants have profited thereby and, unless their conduct is enjoined, Abbott's reputation and goodwill will continue to suffer irreparable injury that cannot adequately be calculated or compensated by money damages. Accordingly, Abbott is entitled to injunctive relief under 15 U.S.C. § 1116.

ELEVENTH CLAIM FOR RELIEF

**Fraud and Fraudulent Inducement
(Against all Defendants)**

240. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

241. Defendants intentionally made or caused to be made knowingly false representations to Abbott and insurers, and intentionally omitted material facts from Abbott and insurers.

242. Namely, Defendants intentionally misrepresented to insurers that the Pharmacy Defendants dispensed authorized domestic FreeStyle test strips when, in fact, they dispensed diverted international FreeStyle test strips. As Defendants knew, these misrepresentations were inadvertently passed along by the insurers, which in turn caused Abbott to pay the insurers rebates.

243. Defendants never informed Abbott or the insurers, that they have been selling diverted international test strips, or that they had submitted false NDC numbers in insurance reimbursement claims.

244. Defendants made or caused to be made these false representations and material omissions with the intent of defrauding Abbott.

245. Defendants knew and intended that Abbott would rely on their false representations and material omissions and, as a result, would incorrectly pay rebates.

246. Had Abbott known the true facts regarding Defendants' fraud, it would not have paid rebates to the insurers for the diverted international test strips.

247. As a result of Defendants' conduct, Abbott has suffered significant injury.

TWELTH CLAIM FOR RELIEF

Aiding and Abetting Fraud (Against all Defendants)

248. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

249. Each Defendant intentionally provided substantial assistance to the others in advancing the fraud against Abbott.

250. Each Defendant either directed a Pharmacy Defendant or endorsed the direction of a Pharmacy Defendant to fraudulently adjudicate the sale of diverted international FreeStyle test strips as domestic FreeStyle test strips in order to profit from the higher

reimbursements and rebates associated with the latter.

251. All Defendants knowingly hid the fraud from Abbott, by omitting to inform Abbott of the fraud.

252. Defendants could not have perpetrated and expanded their fraud without the substantial and material assistance of each other Defendant. Each Defendant benefited from the success of the fraud.

253. All Defendants had actual knowledge of, and substantially assisted in, the fraudulent scheme.

254. As a result of Defendants' conduct, Abbott has suffered significant injury.

PRAYER FOR RELIEF

WHEREFORE, Abbott demands judgment against all Defendants as follows:

- (a) an order entering judgment in favor of Abbott against Defendants, jointly and severally;
- (b) an order temporarily restraining, and preliminarily and permanently enjoining Defendants from engaging in the unlawful behavior described above;
- (c) an order awarding Abbott damages in an amount to be determined;
- (d) an order awarding Abbott trebling of damages;
- (e) an order awarding Abbott pre-judgment and post-judgment interest;
- (f) an order awarding Abbott punitive damages;
- (g) an order awarding Abbott reasonable attorneys' fees and other costs; and
- (h) for such additional relief as the Court finds just, equitable, and appropriate.

JURY DEMAND

Abbott hereby requests a jury trial on all claims and issues asserted in the Complaint.

DATED: October 9, 2015
New York, New York

By:



Geoffrey Potter
gpotter@pbwt.com
Aron Fischer
afischer@pbwt.com
Jeremy A. Weinberg
jweinberg@pbwt.com
R. James Madigan III
jmadigan@pbwt.com
Matthew Funk
mfunk@pbwt.com

PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
Tel: (212) 336-2000
Fax: (212) 336-2222

Attorneys for Plaintiffs Abbott Laboratories, Abbott Diabetes Care Inc., and Abbott Diabetes Care Sales Corporation